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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
WEST PALM BEACH DIVISION

CASE NO. 20-md-02924-ROSENBERG

IN RE: ZANTAC (RANITIDINE) .
PRODUCTS LIABILITY . West Palm Beach, FL
LITIGATION. . March 2, 2021

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DISCOVERY HEARING (through Zoom)
BEFORE THE HONORABLE BRUCE REINHART
UNITED STATES MAGISTRATE JUDGE

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1 *THE COURT:* Okay. Let me make sure we have Ms. Finken
2 and Mr. Oot, our first people who are going to be talking.

3 Mr. Oot, good afternoon.

4 *MR. OOT:* Good afternoon your Honor.

5 *MR. MADERAL:* Your Honor, this is Frank Maderal. Ms.
6 Finken is having a little bit of a technical issue.

7 *THE COURT:* No problem, Mr. Maderal. Thank you.

8 Mr. Oot, if you want to turn off your camera until she
9 gets here, that is fine. If you want to leave it on, that is
10 fine.

11 *MR. OOT:* Thank you, your Honor.

12 *MR. MADERAL:* Your Honor, this is Frank Maderal again.
13 Ms. Finken has joined.

14 *THE COURT:* Wonderful. Thank you. Mr. Oot, if you'd
15 turn on your camera when you are ready, and Ms. Finken, once
16 you get settled.

17 All right. Good afternoon, everybody. This is In Re:
18 Ranitidine Multi District Litigation, Case Number 20-2924.

19 We are here this afternoon for two discovery hearings,
20 one relating to some residual issues relating to a GSK
21 deposition scheduled for tomorrow, and the other relating to a
22 number of issues that were raised relating to the 30(b)(6)
23 depositions of the generic Defendants.

24 With that, let me begin with the residual GSK
25 deposition issues. Let me have counsel make their appearances.

1 I'll start with counsel for the Plaintiff. Let me remind
2 everyone, as we always do, please state your name before you
3 speak so that the court reporter can make a record for us all.

4 *MS. FINKEN:* Good afternoon, Tracy Finken on behalf of
5 Plaintiffs.

6 *THE COURT:* Good afternoon, Ms. Finken.

7 *MR. OOT:* Good afternoon, your Honor, Patrick Oot on
8 behalf of GSK.

9 *THE COURT:* Good afternoon. Just a preliminary
10 question, counsel, is anything under seal for purposes of this
11 proceeding? I know we were looking through some of the
12 materials and it wasn't clear to us if anything had been filed
13 under seal. Ms. Finken, if you could just educate me.

14 *MS. FINKEN:* Your Honor, in relation to the dispute
15 memorandums that were filed on behalf of the generic issues,
16 there were exhibits that were attached to that that would need
17 to be filed under seal due to confidentiality designations.

18 Because they are not on the docket they were not sent
19 to your Honor under seal, but should they need to be docketed,
20 they would need to be filed under seal based upon some of the
21 confidentiality designations on those documents.

22 *THE COURT:* Okay. Well, let's see if we actually
23 utilize those documents during the hearing. If we do, if you
24 and your colleagues alert me that we are delving into that
25 area, then after the hearings are over, I will direct the

1 parties to file their memoranda on the record and anything that
2 should under seal should be filed under seal.

3 Mr. Oot, are you aware of anything under seal for
4 purposes of at least the GSK part of the proceeding?

5 MR. OOT: No, your Honor.

6 THE COURT: Okay. Thank you both for clarifying that.

7 I know I got a notice that the deposition is set for
8 tomorrow. I just wanted to make sure that before the
9 deposition occurs were there any residual issues that needed
10 intervention from the Court. I know we had a brief hearing on
11 Friday, I know there has been a lot of back and forth through
12 the special master and with each other, and I want to thank the
13 parties for their efforts to come to agreement on this.

14 I didn't want the deposition to get started and not
15 have all the loose ends tied up. Ms. Finken, let me turn to
16 you.

17 MS. FINKEN: Yes, your Honor, we had a lengthy meet
18 and confer yesterday morning where we discussed some of the
19 issues. The Defendants' counsel is going to get back to us
20 with some open questions we have that are relative to the
21 motions that we filed.

22 For purposes of the deposition tomorrow, I don't think
23 that there is anything in the motions that would hold up moving
24 forward with the depositions. It would be more so the remedy
25 on the back end should we need to take another deposition of

1 this witness, which is obviously something that I don't think
2 would need to be decided today.

3 What we wanted to do is try to work through these
4 issues over the next few days with counsel, and at this time
5 seek a continuance and reschedule the PTO 32 hearing should we
6 need to do so after the deposition concludes.

7 *THE COURT:* Great. Thank you. Mr. Oot.

8 *MR. OOT:* Yes, your Honor, I would agree with
9 Ms. Finken that the parties have come to at least a short-term
10 agreement on our moving forward with the deposition. We look
11 forward to resolving all of the issues without your
12 intervention and we look forward to that.

13 *THE COURT:* Very good. I won't be offended if you
14 don't need me.

15 For now, if you need to -- Ms. Finken, what is your
16 preference, do you want me to just set another date and time
17 for us to get together, or should I just deem the issues
18 temporarily resolved and I'll wait to hear from the parties if
19 you need another date?

20 *MS. FINKEN:* I think the way that we left it when I
21 spoke to -- it wasn't Mr. Oot yesterday, it was Mr. Cheffo and
22 Mr. Sachse. We had left it that we would seek another date for
23 after the deposition, towards the end of the week or early next
24 week, so that we could try to work through these issues in the
25 meantime. Then, if we could not, we would come back in front

1 of your Honor.

2 I didn't want to necessarily take down the motion
3 because I don't know for sure that we will actually be able to
4 get it resolved. My preference would be that we set another
5 date in the meantime while we continue to try to work through
6 the issues.

7 *THE COURT:* Okay. So, I can give you either Friday, I
8 am wide open this Friday, or I could give you Monday other than
9 between 1:00 and 2:30.

10 *MS. FINKEN:* Friday is fine with me, your Honor. I
11 don't know Defense counsels' availability, but Friday would be
12 fine with me.

13 *THE COURT:* Mr. Oot.

14 *MR. OOT:* Your Honor, Friday is a problem for me. Mr.
15 Sachse might also want to be in this upcoming case management
16 conference. I might suggest, at least for my schedule, Monday
17 afternoon might be best if it has to be.

18 *THE COURT:* Why don't I do this, I will set it for
19 Monday at 12:30 -- no, I'm sorry, I have a one o'clock.

20 Monday at 2:00, we'll set it down. That will give you
21 the entire weekend. You can do nothing all weekend but try to
22 resolve your issues and I'll give you extra time to do that.
23 Monday at 2:00 p.m. we will reconvene and if it turns out you
24 don't need it -- let's just plan to get on the phone with you,
25 whether you think you need it or not, and you can give me a

1 final report. That way we can close the loop on this.

2 While I have you, let me ask one other question. In
3 going back over the submissions in my materials, I see there is
4 a significant deadline on March 15th for production from GSK,
5 and as I recall at the last -- one of our the last hearings,
6 the indication was that GSK was working valiantly to meet their
7 deadline.

8 Mr. Oot, does it still look like you are you going to
9 land the plane on time on the 15th?

10 *MR. OOT:* We are working on that right now, your
11 Honor. I'd say that there are issues that we are working
12 through with Plaintiffs. That will be a discussion, perhaps,
13 that we could have on Monday. Right now, I couldn't say with
14 certainty that we are going to meet the full completion of
15 everything on the 15th.

16 *THE COURT:* Okay. Work it out with each other,
17 obviously. If you don't meet it, as I said before, if somebody
18 misses a deadline and the other party thinks they are entitled
19 to a remedy, you are certainly entitled to ask for that remedy.

20 Given the relationship here, I will assume that even
21 if you are going to miss the date for some things, you will
22 work with Ms. Finken to try to minimize any prejudice so the
23 case can keep moving. I will leave that alone until I see you
24 on Monday.

25 Anything else, then, Mr. Oot, that you think we need

1 to raise on the GSK matter?

2 *MR. OOT:* No, thank you, your Honor.

3 *THE COURT:* With that, Ms. Finken, anything else on
4 the GSK matters?

5 *MS. FINKEN:* No, your Honor. We can talk about the
6 March 15th deadline on Monday. We have been advised that they
7 will not meet the March 15th deadline, but certainly we can
8 discuss that in a more fulsome manner on Monday.

9 *THE COURT:* Maybe the world will change between now
10 and Monday. They will get a boost of energy and they'll get it
11 done in time. We'll cross that bridge when we get there.

12 *MS. FINKEN:* We can only hope.

13 *THE COURT:* Exactly right. Candidly, counsel, that is
14 why I really don't like to try to delve into these things until
15 there is something to delve into because the world does change
16 a lot, particularly in a case like this, seven days is a
17 lifetime. We will see what happens between now and then. I am
18 always happy to talk to you about those sorts of issues, but I
19 try to avoid ruling on them until there is really something to
20 rule on.

21 With that, I will excuse Mr. Oot. Thank you very
22 much.

23 Ms. Finken, I think you are staying on for the next
24 matter. We will now transition over to the generic 30(b)(6)
25 issues. The first issue we are going to take up is the

1 manufacturing issue. My understanding is that Mr. Barnes is
2 going to speak to that for the Defense, and that he has other
3 commitments around 4:15. God forbid we are still on this topic
4 in two hours, but I want to make sure Mr. Barnes had plenty of
5 time to be heard. Good afternoon, Mr. Barnes.

6 *MR. BARNES:* Thank you, your Honor, and thanks for
7 accommodating my schedule. Thanks to Ms. Finken as well.

8 Your Honor, good afternoon, Richard Barnes. I am
9 appearing today in my role as co-liaison counsel for the
10 generic Defendants.

11 *THE COURT:* Hold on. Before you go on, Mr. Barnes,
12 let me do a little bit of housekeeping as well.

13 I guess relating to -- I got an email late last night
14 when I had plenty of other reading to do, so I can't tell you
15 that I read it particularly carefully, even though I know it
16 was not very long, which seemed to indicate there were some
17 other issues that the parties -- related to the generics that
18 needed the Court's involvement, and maybe some of them will be
19 mooted out by what we do today, maybe they won't.

20 I was going to offer you a hearing on Thursday to
21 address the issues that were raised in that email. I have the
22 whole day wide open.

23 Ms. Finken, what is your pleasure?

24 *MS. FINKEN:* I am perfectly wide open on Thursday as
25 well, your Honor, so happy to appear before you at the Court's

1 convenience.

2 *THE COURT:* Mr. Barnes, are you the right person to
3 ask about this topic or do those go to some of your co-counsel?

4 *MR. BARNES:* Let me defer that to Mr. Yoo. I am tied
5 up Thursday and Friday, or Mr. Henry. I will not be
6 representing the generics on Thursday, I am just booked all
7 day, but maybe Mr. Henry can address that.

8 *THE COURT:* Mr. Henry, what is your pleasure for
9 Thursday?

10 *MR. HENRY:* Your Honor, it's Terry Henry for Apotex
11 Corp. I can make available Thursday if these issues need to go
12 to a PTO 32 hearing.

13 *THE COURT:* Ms. Finken, since you sent the email, how
14 much time do you think we will need for the PTO 32 hearing on
15 Thursday?

16 *MS. FINKEN:* I don't believe that we will need as much
17 time as we need today to work through the notices of deposition
18 issues, so I would say maybe an hour, hour and a half, your
19 Honor. They are relatively simple issues.

20 *THE COURT:* Mr. Henry, any preference, morning or
21 afternoon?

22 *MR. HENRY:* Your Honor, early afternoon would be the
23 best. I actually do have something on my calendar at
24 4:00 o'clock that afternoon, so early afternoon would be best.

25 *THE COURT:* We'll schedule that for one o'clock on

1 this Thursday for a PTO 32 on the issues that were sent by
2 email last night. I will set aside two hours, from 1:00 to
3 3:00 on Thursday afternoon. We'll enter an order to that
4 effect.

5 Do I need further briefing from you all or are these
6 the kind of issues that we can talk out in person?

7 Ms. Finken, what is your sense?

8 *MS. FINKEN:* They are relatively simple issues
9 relating to deposition scheduling and timing, and numbers of
10 depositions per day. It might be easier to put together a
11 short memorandum for your Honor just to solidify the issues in
12 advance for your sake. I am happy to do that, I think it might
13 be helpful for you.

14 *THE COURT:* I have read PTO 54 and PTO 16, so I am
15 familiar with what they say. I am always happy to get briefing
16 from you, but I also am mindful that every time you are
17 briefing something for me you are not only working on other
18 aspects of this case, and you have a judge and a magistrate
19 judge telling you, get on your horse and ride. So, I don't
20 want to pull you away if you are making good progress on other
21 things.

22 Mr. Henry, what is your sense about briefing, if any,
23 for Thursday?

24 *MR. HENRY:* Your Honor, a little table setting is
25 always helpful.

1 *THE COURT:* Okay. How about by five o'clock on
2 Wednesday, then, send me a joint submission. Again, it doesn't
3 have to be formal, just tee up what the issues are.

4 I know from looking at PTO 54 and PTO 60, I believe
5 the order from Judge Rosenberg was that the generics were
6 supposed to give deposition dates to the Plaintiffs for
7 manufacturing depositions, storage and transport depositions, and PD depositions.
8 So, I am assuming everybody complied and those dates have been
9 given.

10 I am assuming this is not going to be like law school
11 where everybody votes to be the last person called on in class,
12 and wants their depositions on the last day of the month and
13 we're left with 23 people all of whom want to be deposed on the
14 same day.

15 I will tell the parties I will not hesitate to play
16 teacher and call on you and unilaterally order the depositions
17 to occur on the days that I think they should occur. So, I
18 encourage you to talk to each other and work it out.

19 You have 23 Defendants, you have 20 plus days in
20 April, 20 plus days in May. Numerically, you have billions and
21 billions of possible combinations to get everybody done in the
22 timeframe that you have been given. So, I hope you will be
23 able to find one of those billions and billions of combinations
24 that works for you and I don't have to intervene.

25 We can take that up more fully on Thursday.

1 *MS. FINKEN:* Thank you, your Honor. Hopefully, with
2 that sage guidance, we will be able to work it out in advance
3 of the hearing.

4 *THE COURT:* I have no doubt you will.

5 Let's then turn to the specific issues that were
6 noticed for today. I also did want to just clarify one other
7 thing for the parties because I really am trying not to set a
8 precedent here.

9 As you know, it is generally my practice not to rule
10 on 30(b)(6) topics in advance of a deposition. I really do
11 think the better practice is to have the witness appear, have
12 the questions asked, and then I can rule on a specific record
13 on a specific question. In the normal case, I think that is
14 the advisable way to do it.

15 However, I recognize this case is anything but normal.
16 I recognize that a number -- all of the issues we are going to
17 address today are really cross-cutting issues that go across
18 lots of depositions, and the rulings on these, on the one hand,
19 are going to affect substantially the burden that may be
20 imposed on the Defendant to prepare a witness and/or the scope
21 of the deposition that the Plaintiff is allowed to take.

22 I think given the timeframes that we are dealing with,
23 making you, at least initially, go to deposition, ask the
24 questions, get a transcript, because not everybody is as fast
25 and efficient as Mrs. Stipes, wait to get a transcript, file

1 the transcript with me, have me reconvene the hearing, have me
2 rule, and then potentially have to reconvene the deposition, is
3 simply not in the best interest of moving this case forward at
4 this stage.

5 That is why I am having this hearing today, because I
6 think, under my duties under Rule 1 to efficiently and cost
7 effectively move the case along, I am making an exception to my
8 usual rule, but I don't want everyone in this case to think
9 that every 30(b)(6) deposition you get to have a PTO 32 hearing
10 in advance.

11 That is my goal for today, and there may be specific
12 topics that I do defer to you and say, go ask the specific
13 question, but I will try to at least address all the
14 cross-cutting issues.

15 Thank you for indulging me to make those opening
16 remarks and set the table. Let's turn to the manufacturing
17 issues.

18 I have the motion that was submitted, I have the
19 Plaintiffs' response. I am going to kind of use the Defense's
20 motion as a road map. Let me see what the topics are. Global
21 issues. Okay.

22 So, the first issue seems to relate -- is the argument
23 that because the manufacturing defect claims have been not
24 repled in the new complaints, that certain discovery topics
25 should not be permitted.

1 Mr. Barnes, thank you for being patient. Let me ask
2 you to tee that up or frame that however you want to best frame
3 it.

4 *MR. BARNES:* Thank you, your Honor. Richard Barnes,
5 counsel for Perrigo, and appearing today as co-liaison counsel.
6 There are three motions today, and we appreciate your Honor
7 taking these on to give the parties some guidance.

8 I think we did make some progress in the meet and
9 confers, we did get some things resolved, but as to these
10 overarching issues which the generics tried to put forward in
11 the three motions to give your Honor a sense of these
12 cross-cutting issues that need to be resolved on the front end,
13 let me go right to the manufacturing issues that we have here.

14 To set the stage on how we looked at it, last night,
15 Special Master Dodge sent an email to Mr. Yoo and basically
16 advised that perhaps we should advise you up front of the one
17 thing that we would most like you to resolve at today's hearing
18 to move this process forward.

19 I looked at it and I thought about it. I didn't
20 really confer with my colleagues who were a bit busy this
21 morning, as you might expect, but from my perspective, it
22 simply is this, that the Plaintiffs have not adjusted the scope
23 of any of these notices to match their now much more narrow
24 claims against the generic Defendants.

25 So, let's -- to set the stage, as you know, Judge

1 Rosenberg's preemption order dismissed with prejudice all
2 design claims about the molecule itself, as well as all claims
3 for labeling other than permitting them to attempt to replead
4 on expiration dates.

5 She held that the manufacturing defect claims were
6 dismissed, but permitted the repleading of a cause of action to
7 see if they could state a cause of action under state law for a
8 manufacturing defect that wasn't preempted or otherwise barred.

9 So, the point of the matter is this: After a lot of
10 meet and conferring in January, when we were trying to figure
11 out what the claims would be and trying to negotiate some of
12 these issues on these deposition notices, the generics were not
13 apprised of what the claims would be, except that we understood
14 from the meet and confers that the Plaintiffs would plead
15 everything to the maximum extent provided under Judge
16 Rosenberg's order.

17 When the pleadings were filed earlier this month that
18 was not the case, and specifically and of special relevance to
19 this discussion is that the Plaintiffs elected not to pursue a
20 manufacturing defect claim.

21 It is our position that for the purposes of
22 determining the scope of discovery, as there is no claim that
23 the manner in which the Ranitidine molecule was manufactured to
24 make it defective or in some way unreasonably dangerous, the
25 issues as to manufacturing have got to be very limited to the

1 claims that have been asserted.

2 So, the Court's preemption ruling, combined with the
3 Plaintiffs' choice not to replead this cause of action, has
4 served to drastically narrow the claims at issue against the
5 generics.

6 So, what I think we are asking for today, a
7 cross-cutting issue, is that the Court enter a protective order
8 that reflects the issues that have been pled, the claims that
9 have been made, and to keep it focused on a proportionate
10 amount of information directed to these claims that remain
11 against the generics.

12 So, that is kind of -- as I summarize where we are, we
13 think that the notices are simply at high tide and not related
14 to the narrow substance of the claims as pled.

15 Specifically as to manufacturing of finished
16 Ranitidine products, we agree that the Plaintiffs, under the
17 instructions from the Judge and how we understand them and from
18 your Honor, that the Plaintiffs should be entitled to question
19 generic witnesses about the stability testing that was done on
20 products over time and the methods that the generic companies
21 used to assess the rate of degradation of the Ranitidine
22 molecule over time in an effort to set the expiration date and
23 the conditions of storage.

24 Those are the two claims that are in the case. So,
25 that is what we think the focus must be on, and in that they

1 would understand the issue of how -- the care that was taken to
2 set the expiration dates, as well as why, or why not, to give
3 them their due, that the storage conditions or the transfer
4 conditions were not satisfied by the generic Defendants.

5 So, as you read their amended complaint and you read
6 the preemption briefing, there is absolutely no dispute that
7 the way the generic companies, or any pharmaceutical company
8 sets these parameters, is through stability testing, and it is
9 the stability testing that establish what the expiration date
10 should be, and also what storage conditions would be an
11 unacceptable or acceptable temperature or humidity.

12 So, the policies and procedures directed to this
13 question are relevant and we have produced them. They have had
14 them against many of the generic Defendants since July. They
15 have had the results of the stability testing since July. They
16 know the parameters that were set. They know the post recall
17 testing that was done on the molecule itself. Ms. Finken has
18 attached some of the work to her motion.

19 So, the primary area of disagreement can be summarized
20 as this, it is because there is no pending claim as to
21 manufacturing, this deposition notice is disproportionate in
22 asking manufacturers to prepare a witness to walk through every
23 aspect of the manufacturing process for Ranitidine, the quality
24 issues relating to that, the quality management issues, and it
25 is simply beyond the scope.

1 It is especially disproportionate and unreasonable to
2 ask the generic Defendants about aspects of the manufacturing
3 process that have absolutely no bearing on the remaining claims
4 as to expiration date, and storage and transportation
5 conditions.

6 So, as we understand what the Plaintiffs are asking
7 for, we believe that we do not want our witnesses to be prepped
8 and sit for a deposition on issues that are entirely outside
9 the scope and collateral.

10 There are 43 or so topics on the manufacturing notice.
11 I don't know why I agreed to take that on, but the first topic
12 is emblematic of our issue. I will read it to your Honor.

13 We are to produce a witness to be prepared to explain
14 the specific process or processes used to manufacture
15 Ranitidine freebase, Ranitidine active drug substance (API) and
16 Ranitidine finished product of your RCPs, which is Ranitidine
17 containing products, including, but not limited to, the drug
18 substance, synthesis, purification, crystallization or
19 recrystallization process, testing of the pH values of the drug
20 substance, the grade of the drug substance, solvent
21 composition, the solvent volume, water concentration, and
22 crystal morphology.

23 Given that it is not alleged that the physical
24 properties of the Ranitidine molecule is defective in
25 manufacture, all this detail is besides the point and it is

1 directed to issues that are not in the complaint.

2 Because the Court has held the questions about the
3 design of the Ranitidine molecule as preempted, and there is no
4 remaining manufacturing claim, Plaintiffs simply can no longer
5 allege that somehow these physical properties of the Ranitidine
6 molecule produced in this manufacturing process makes the
7 molecule defective.

8 What is relevant is how we set our expiration dates
9 and our storage conditions and the work and testing that went
10 into that process. That is what is at issue, and that is what
11 we should be held to testify about.

12 *THE COURT:* Okay. Let me -- I didn't mean to cut you
13 off. Go ahead.

14 *MR. BARNES:* I just wanted to say, I am not saying
15 there are no manufacturing witnesses -- you know, that there is
16 no possible question. I guess what we are saying is, they can
17 ask the manufacturing witnesses about whether -- the Ranitidine
18 API, to the extent that a manufacturer would know that because
19 many manufacturers don't manufacture API, or the Ranitidine
20 finished products that are manufactured in the United States
21 and emerge from this manufacturing process.

22 The question is whether they demonstrate a rate of
23 degradation that should have yielded a different -- a shorter
24 expiration date, or a different transport condition or storage
25 condition, because that goes to their remaining claims, and

1 that is fair game.

2 To summarize, we should not be forced to answer
3 questions about a theory or a cause of action that is not
4 alleged in the case and would require hours and hours of work.

5 *THE COURT:* Okay. Thank you. I will give you a
6 chance to be heard in a second. I will come back to you.

7 I was looking at your chart here, and you objected, I
8 think, 32 times that the topic does not apply to a generic
9 Defendant that did not manufacture API or Ranitidine containing
10 products. First of all, that is not a legal objection.

11 And second of all, then there is no burden to prep a
12 witness to simply say, we didn't do it. I don't see what the
13 burden is to simply have the witness say, that is not what we
14 did. So, I hear you, I see that. To the extent that is your
15 objection, I overrule that objection.

16 Ms. Finken, let me hear you in response. The argument
17 that they are making is, if this evidence is relevant to your
18 currently existing claims, then it is relevant to your
19 currently existing claims, and that is all that I am focused
20 on, are currently existing claims.

21 From reading your materials, if you want to address
22 this, this seemed to me to be the issue that I was having some
23 confusion about, is whether -- is the Plaintiff's theory that a
24 Ranitidine molecule is inherently unstable and will degrade
25 regardless of how you make it, or just by the nature of what

1 the chemical makeup is? If you put these -- I am not a
2 chemist -- but if you put these molecules together, it is
3 eventually unstable no matter where you get your carbon from,
4 or your nitrogen from, or whatever else; or is it the
5 Plaintiffs' theory that different formulations of the molecule
6 will degrade at different rates, et cetera?

7 If you could address that in your remarks, that would
8 be helpful to me.

9 *MS. FINKEN:* Sure, your Honor. Just to address that
10 up front, your question, and specific to what Mr. Barnes just
11 said -- I apologize, Ms. Stipes, it is Tracy Finken for
12 Plaintiffs. Please, if I am going too fast or you can't hear
13 me, I will be happy to repeat it.

14 To address your question and to address what Mr.
15 Barnes just admitted, he admitted that the rate of degradation
16 of the product is relevant to the claims that we have brought
17 in this case, and he admitted that that is relevant to the
18 expiration dates and the storage and conditions of the product.

19 The Defendants' own documents identify that different
20 manufacturing processes affect the rate of degradation of the
21 product and they affect the variability of NDMA formation in
22 the product, and they affect how the expiration dates are set,
23 and the requisite storage and transportation conditions, which
24 are all directly tied into the claims that we have brought
25 against the generic manufacturers in this case. That is one

1 point.

2 The second point, your Honor, as far as the inherent
3 instability of the product, there are counts within our
4 complaint that allege that the molecule itself is inherently
5 unstable and degrades to form Ranitidine -- to form NDMA, I am
6 sorry. However, with that being said, there are different
7 manufacturing processes and different conditions that affect
8 the variability of the formation of NDMA within the product.
9 They affect the degradation rates and they affect the
10 variability of NDMA within the different products.

11 This is information that was admitted to by all the
12 Defendants in their root cause analyses that they submitted to
13 regulatory agencies here in the U.S. as well as foreign
14 regulatory agencies. That goes through all generic Defendants
15 and the brand Defendants.

16 Another issue that I just -- I want to point out on
17 that is that the generic manufacturer Defendants also
18 manufacture product for the brand Defendants. So, to the
19 extent that the manufacturing processes are relevant to other
20 products within this litigation, I just wanted your Honor to be
21 aware of that.

22 For example, Dr. Reddy's manufactured product for GSK,
23 Apotex manufactured product for the retailer Defendant store
24 brand products. So there is a lot of, for lack of a better
25 word, incestuous relationships across Defendants as far as the

1 manufacturing processes and the Ranitidine that was ultimately
2 put on the market.

3 *THE COURT:* They would call it intra-industry
4 efficiencies.

5 *MS. FINKEN:* Yes, that is a much better way of
6 phrasing it, your Honor.

7 Just going back, though, to your Honor's point, I just
8 wanted to point this out, that you may have noticed in the
9 submissions to your Honor that the Defendants did not, as
10 required by PTO 32, certify that the dispute resolution motions
11 were ripe, that there was a meet and confer process with
12 Plaintiffs and a good faith effort to resolve the disputes, and
13 there is a reason for that, your Honor.

14 It is that Defendants cannot certify this in relation
15 to the disputes they raised in their motions because they
16 served almost 50 pages of objections and charts that we heard
17 about for the very first time on Sunday.

18 These objections were never raised as part of the meet
19 and confer process, they were not discussed, so Defendants
20 cannot certify truthfully to the Court that such had taken
21 place as required to do under PTO 32.

22 *THE COURT:* I saw that loud and clear in your
23 response, you said it a lot, and you said it loudly, and I
24 ceded that and I considered that, but in looking at what the
25 specific objections were, the line by line, I went through the

1 whole chart, it seemed to me that if I simply resolve the
2 issues that are raised in the memo that clearly were fully
3 vetted, my impression was that would resolve 80 to 90 percent
4 of the specific objections that were raised.

5 Maybe they weren't raised in a manner that you had a
6 specific meet and confer about topic 17, but my impression was
7 that if I rule on the issues that are fully vetted in the
8 motion I will resolve most of those issues.

9 I heard that argument and I considered whether I
10 should address a waiver question, but I am not going to do that
11 because I really do think the issues that were properly vetted
12 will resolve those issues.

13 *MS. FINKEN:* Thank you, your Honor, and I hope that is
14 the case because the express agreement between the parties that
15 was memorialized in PTO 60 contemplated that the parties would
16 have this meet and confer process over the course of the month
17 of February and that we would resolve all disputes today at
18 this PTO 32 hearing.

19 That was the process that was contemplated, it was the
20 process that was agreed upon and sent to the Court in the
21 February 4th letter of Mr. Henry, and it was ultimately
22 memorialized in PTO 60.

23 I can personally state, I have gone back and looked, I
24 have spent almost 30 hours over the month of February engaging
25 in meet and confers with the Defendants, specifically the

1 generic Defendants, on these 30(b)(6) notices and on PTO 60.

2 So, to the extent that items were not raised during
3 those discussions, it is a little disturbing to me that they
4 are being raised at the last minute today, but I will move on
5 from that, your Honor.

6 *THE COURT:* All right. Great. Let me just circle
7 back, though, to make sure I understand your answer to my
8 question, which you answered, but I want to make sure I
9 understand your answer.

10 Your position is that, first, as a factual matter,
11 different -- this my phrase -- different formulations, but
12 Ranitidine which is manufactured from different ingredients are
13 using different manufacturing processes. Two different
14 Ranitidine tablets, or Ranitidine -- I guess it's a tablet, I
15 never took it -- that are manufactured in two different
16 manufacturing processes using different APIs and different
17 processes can have different degradation rates. That is pled
18 and that is your theory pled.

19 Again, I didn't read all five thousand pages, but that
20 is pled in your complaints?

21 *MS. FINKEN:* Your Honor, that is a factual matter that
22 is pled in the complaints, and I can also tell you that for
23 purposes of this dispute and what we are here to determine
24 today, is whether or not our side, the Plaintiffs, can question
25 the generic manufacturer Defendant witnesses in relation to

1 documents that they already have produced, that they have
2 produced to the regulatory agencies, they have produced already
3 in large part to us. So, there is no burden on them to go and
4 seek out these documents for production.

5 We are seeking testimony relating to the manufacturing
6 processes and the use of such things as solvents in the
7 manufacturing process.

8 Defendants' position is that Plaintiffs should not be
9 permitted to question their corporate witnesses regarding these
10 documents that have already been produced and which were
11 submitted in relation to the root cause analyses of how NDMA
12 came to be in their Ranitidine products. This issue goes to
13 the very heart of Plaintiffs' entire case, it is a
14 cross-cutting issue that cuts across all theories of liability,
15 across all Defendants.

16 Each Defendant was required by the FDA to submit a
17 detailed root cause analysis to the FDA and other regulatory
18 bodies answering certain questions related to the mechanism of
19 action as to how NDMA was forming in Ranitidine. Many of the
20 generics did that. Aurobindo, Dr. Reddy's, Apotex, and others
21 have done that.

22 Some of these documents were submitted to the Court as
23 exhibits to our memo for the Court to see firsthand the level
24 of detailed analyses of their manufacturing processes that the
25 generics submitted to the regulatory agencies on these very

1 specific issues, and how they detail with great specificity
2 these manufacturing processes, the use of solvents, the use of
3 excipients, et cetera, that may have played a part in the
4 formation of NDMA, the rate of formation of NDMA, the rate of
5 degradation of Ranitidine that forms NDMA, and the levels of
6 NDMA in the products themselves.

7 This questioning of a witness is not about a
8 manufacturing defect, it is not a manufacturing defect claim.
9 Mr. Barnes was right about that. However, it is about
10 mechanism of action, how the Defendants themselves concluded
11 that NDMA was forming or not forming. It goes directly to the
12 defenses that will be propounded in this case. It is about a
13 notice issue and how that notice may or may not affect the
14 underlying claims of negligence and design defect.

15 It is about causation, and I can only assume, your
16 Honor, that the Defendants are going to rely upon their own
17 scientific analyses of their processes that they reviewed for
18 purposes of their investigation into how this was occurring and
19 how much NDMA was being formed and how quickly.

20 I can imagine that the generic Defendants are not
21 willing to stipulate to the mechanism of action and the amount
22 of NDMA in each pill and how it forms over time and is subject
23 to different degradation and formation of NDMA invariability.

24 Just to be clear, perfectly clear, when I speak about
25 the root cause analysis that the generics prepared for the FDA,

1 I am referring to a set of documents that were prepared as a
2 culmination of their entire investigation into the
3 manufacturing processes, the use of solvents, the use of
4 excipients, any potential contamination, the molecule itself,
5 the degradation of the product, the stability of the product,
6 et cetera.

7 Defendants have been stating repeatedly that it is too
8 big of a burden or disproportional to gather documents and
9 prepare a witness to testify about manufacturing process;
10 however, these documents been gathered, many of them have
11 already been produced. The generic manufacturers must submit
12 detailed specifications of the manufacturing processes used for
13 their products.

14 The generic manufacturers have to do this whether
15 they physically manufactured the product in the U.S., whether
16 it is their foreign affiliate who manufactured the products for
17 them in India, whether it is a third party manufacturing for
18 them on Mars, it does not matter. The generic Defendants have
19 a responsibility to provide that information to the FDA, and
20 they have done so, and they have provided that information to
21 us as well.

22 They have done their own scientific investigation of
23 those processes. They have come up with conclusions on NDMA
24 formation and how and why that is happening, and how much in
25 terms of the degradation of the product. And for Plaintiffs

1 not to be able to question their witnesses about those
2 conclusions that they are going to rely upon for purposes of
3 their defenses in this case would be unfairly prejudicial to
4 us.

5 So, for that, your Honor, we would request that you --
6 respectfully, we would request that you deny their motion for
7 protective order in relation to the manufacturing notice.

8 *THE COURT:* Let me turn back to Mr. Barnes.

9 Mr. Barnes, so much of the protective order can be
10 predicated upon annoyance, harassment, undue burden. Are you
11 also arguing relevance and disproportionality or are you just
12 relying on Rule 26(c), the grounds for protective order?

13 *MR. BARNES:* Relevance, proportionality, and
14 burdensomeness, your Honor.

15 *THE COURT:* Okay. Let me let you have the last word
16 on the merits in response to Ms. Finken's arguments.

17 *MR. BARNES:* I will not respond to the meet and confer
18 process. I am not waiving anything, though.

19 *THE COURT:* Understood.

20 *MR. BARNES:* I want to go back to first principles,
21 your Honor. They have had these documents since July from,
22 let's say, Apotex. Apotex produced all this stuff in the start
23 of July. They had specific allegations in the original
24 complaint as to solvents, as to manufacturing defect. It was
25 in the original complaint. They abandoned the manufacturing

1 case.

2 What we have now is the manufacturing process yielded
3 a Ranitidine molecule. You asked a question, which is a good
4 one: Does the formulation matter? The formulation is a design
5 issue, it is Ranitidine. The question that remains to be
6 litigated is, given the molecule that came out of this
7 manufacturing process, which is not alleged to be wrong in any
8 way, should you have set a shorter expiration date which,
9 according to their theory, would have had less NDMA in the
10 molecule?

11 Their fundamental issue in this case is at figure 1,
12 is that Ranitidine is inherently unstable and has constituent
13 parts A and B that, through no exogenous force, plays off a
14 molecule called NDMA, and that is their case. Their point is,
15 you should have done a shorter expiration date and you should
16 keep the truck away from the Mojave Desert. That is basically
17 what they are left with.

18 So, they have the physical product itself, they have
19 the Ranitidine tablet from GSK, let's say. Let's keep Mr. Oot
20 out of this as best I can. But still, they look at that and
21 they can measure the NDMA in that tablet, they can measure the
22 original specks of it, and they can basically tell what the
23 amount of NDMA is, and then their experts can say, based on the
24 physical thing itself, that a shorter expiration date would
25 have provided less NDMA.

1 That is their case. It is not that we have had
2 solvents or we have any specific process, it is that you should
3 have had a shorter expiration date or you should have used a
4 different storage condition. They want to boil the ocean and
5 go through the entire manufacturing process.

6 We produced those documents pursuant to a court order
7 while we were litigating the Motions to Dismiss. We all
8 complied and they have had it and they have chosen for tactical
9 reasons not to pursue it.

10 What we are asking is to cabin this to the issues they
11 have pled. If their experts want to look at the reports that
12 were filed pursuant to FDA directives, we can talk about that.
13 Right now it is about what should the company produce on its
14 manufacturing and manufacturing witness. It is not in the
15 case.

16 The formulation is the design, and to the extent that
17 one design yields a morphology that is slightly different from
18 the other, you look at the pill itself, the tablet itself, and
19 you will see the morphology. Then she can have an expert say
20 morphology A is more prone to degradation than morphology B.
21 It's not known as to how you got morphology A or B.

22 Neither is it the product of a manufacturing defect.
23 After the process, you have the physical inanimate object, the
24 physical properties can be measured, and that is expert
25 discovery, and that will happen later in the case. They have

1 the scientific work produced line after line by many
2 Defendants. They have a published work by GSK in its
3 scientific literature which goes through the process chapter
4 and verse.

5 We are concerned that they are making this through the
6 back door, again, a manufacturing defect case without pleading
7 it. They are making it about the formulation, which is your
8 Honor's question, that is preempted.

9 To the extent this one pill is different than the
10 other, then you measure it and you have the difference, but as
11 to how it got to that point is irrelevant.

12 We are happy to have her basically look at the
13 stability tests and see what we should have been on notice of
14 in terms of setting the expiration date and the conditions of
15 storage. That is their case, that is what we are here to talk
16 about.

17 *THE COURT:* Thank you very much.

18 *MS. FINKEN:* Your Honor, can I respond just briefly?

19 *THE COURT:* Sure.

20 *MS. FINKEN:* I just want to point out again that the
21 manufacturing process and the testing that is done as part of
22 the manufacturing process is relevant to how the Defendant --
23 how the Defendants set the expiration dates because the
24 degradation issues and stability of the product changes based
25 upon how the manufacturing process is. This is true.

1 I would challenge Mr. Barnes, if he is going to
2 continue with this line of argument, that he then should
3 stipulate to the Court on behalf of all of the generic
4 manufacturers that no generic manufacturer will rely on
5 manufacturing processes, API manufacturers, contaminants,
6 solvents, foreign affiliate manufacturers, component part
7 manufacturers, any documents related to the manufacturing
8 processes or root cause analyses, or anything else that they
9 are seeking limitations on scope in terms of defending their
10 claims.

11 So, if Mr. Barnes is willing to stipulate that to the
12 Court, that they are not going to rely on their own internal
13 documents, their own investigations, their own processes that
14 they have evaluated for purposes of this claim, then maybe we
15 don't have a dispute. But I don't think Mr. Barnes is prepared
16 to do that today.

17 *THE COURT:* Again, that is not an issue before me.
18 Based on my ruling, if you all want to have further
19 discussions, you all can discuss away.

20 *MR. BARNES:* Thank you, your Honor.

21 *THE COURT:* Okay. I start, as I always do in these
22 situations, with Rule 26(b)(1), which says that parties may
23 obtain discovery regarding any non-privileged matter that is
24 relevant to any party's claim or defense and proportional to
25 the needs of the case, considering the importance of the issues

1 at stake in the action, the amount in controversy, the parties'
2 relative access to relevant information, the parties'
3 resources, the importance of the resolving the issues, whether
4 the burden or expense of the proposed discovery outweighs its
5 likely benefit.

6 I also have to look at Rule 26(c), which is the
7 protective order rule, which says, a party may obtain a
8 protective order based upon to avoid -- based upon good cause
9 to avoid annoyance, embarrassment, oppression, an undue burden
10 or expense. They sort of bump up against each other.

11 Let me start with 26(b)(1). First of all, I find this
12 evidence is relevant regardless of what the claims are. I
13 agree with Mr. Barnes that there is no manufacturing defect
14 claim. Just because there is no manufacturing defect claim
15 does not lead to the conclusion that the manufacturing
16 processes are irrelevant.

17 They may be relevant to other aspects of the case, and
18 Ms. Finken has articulated a theory of relevance as to why they
19 are relevant to other aspects of the case. So, I do find this
20 evidence to be relevant to the existing claims and defenses in
21 the case, particularly relating to the expiration dates and the
22 storage and transport issues. So I find it is relevant.

23 The question is, is it proportional? I'll start with
24 considering the importance of the issues at stake in the
25 action. As I've said previously, the core of this case, the

1 most important question in this case is, does Ranitidine cause
2 cancer, and under what circumstances does it cause cancer, and
3 did these manufacturers and distributors know that?

4 I think the evidence that is being sought here, and
5 the theory under which it is being sought is central to this
6 case. It is extremely important to the issues at stake in the
7 action.

8 The next issue is the amount in controversy, which has
9 more zeros in it than I can count, so I will concede that there
10 is a lot in controversy in this case.

11 The parties' access to relevant information. Clearly
12 the evidence as to how the generics manufacture their
13 Ranitidine is exclusively within the possession of the
14 generics. I can't expect the Plaintiffs to go get it from
15 somebody else.

16 The parties' resources, I don't know, I don't have a
17 record in front of me. I could speculate that the generic
18 manufacturers probably have more money than the Plaintiffs, but
19 some of these Plaintiffs' lawyers have a lot of money, so I
20 don't know. That one is sort of a wash for me.

21 The importance of discovery resolving the issues is --
22 given that expiration dates and storage conditions are
23 important, how important is this evidence to try to prove that?
24 And I do think it is important.

25 As Ms. Finken has articulated, if the rate at which

1 the product degrades is a function of the ingredients and the
2 process that go into the product -- I am taking her at her
3 representation that that is properly pled.

4 I accept that representation that it is properly
5 pled that the rate of degradation is at some level a function
6 of the ingredients and the manufacturing process, and that the
7 rate of degradation is therefore a factor that goes into how
8 one should set the expiration date, which is a specific claim
9 in this case, that the expiration dates were not set correctly.
10 I find that this evidence that is being requested here is
11 important to resolving that issue.

12 Finally, whether the burden or expense of the proposed
13 discovery outweighs its likely benefit. I hear Mr. Barnes
14 telling me it will be burdensome to prep somebody. I also hear
15 Ms. Finken saying, maybe inferentially, but that really at the
16 deposition as a practical matter the questions are going to be
17 pretty much tied to the documents that have already been
18 produced.

19 If that is going to be the case, perhaps between now
20 and then Ms. Finken can give Mr. Barnes a little more guidance
21 about the specific area she is going to cover and specific
22 documents she is going to ask about.

23 I think to the extent there is an extended burden
24 here, that can be mitigated.

25 So I find, under Rule 26(b)(1), this evidence is

1 relevant and proportional, and under Rule 26(c), I do not find
2 that the Plaintiffs -- that the generic manufacturers have met
3 their burden of establishing undue burden or expense,
4 annoyance, embarrassment, oppression, so I will overrule the
5 request for a protective order on that issue relating to the
6 manufacturing processes and I will allow -- I will just
7 overrule that objection.

8 Let's move to the next one here on the manufacturing,
9 which is the relevant testing should be limited to testing
10 which can detect NDMA as opposed to nitrosamine.

11 Someone is going to have to educate me on this one.
12 Ms. Finken, why don't you tell me what are you asking for.
13 Then I can understand what it is that Mr. Barnes is objecting
14 to.

15 *MS. FINKEN:* That is an excellent question, your
16 Honor. So, what we are asking for in terms of this particular
17 deposition notice, we have very specific definitions of testing
18 that sets forth a list of very specific types of testing, and
19 that testing is all relevant to detecting MDMA, nitrosamines,
20 impurities, and carcinogens within the products themselves. It
21 is testing that the Defendants have used in their root cause
22 analyses, the Defendants have used over time in looking at
23 impurities in the drug product, and we have met and conferred
24 on this issue quite a bit.

25 During that process, I have requested from Defendants

1 multiple times for them to point to specific tests that they do
2 not believe are relevant to this case. They have refused and
3 declined to do so. They continue to make boilerplate
4 objections to the list of testing, and they wanted us to make
5 it more vague, ambiguous, and less specific in terms of the
6 definition of testing, which we did not want to do.

7 We made it very specific for a reason after
8 consultation with our science committee and also looking at
9 their own internal documents.

10 *THE COURT:* If I could stop you. You know a lot more
11 about this than I do, so I am going to have to slow you down
12 just one second.

13 What is a nitrosamine -- what is it you are looking
14 for? What are you trying to get to at the core?

15 *MS. FINKEN:* Nitrosamines is a class of carcinogens
16 which NDMA falls within. So, when we use these terms -- and
17 this is a great point, your Honor, because it is something that
18 we have also discussed with Defendants because they wanted us
19 to limit the term to NDMA.

20 However, when you look at the Defendants' documents
21 themselves, when they reference NDMA, they reference it as a
22 nitrosamine. They reference it as an impurity. They admit
23 that it is a genotoxic impurity and a carcinogen. They use all
24 of these terms as synonyms for NDMA in their own documents, and
25 that is why we have crafted this deposition notice specifically

1 the way that it is.

2 It is based upon the use of the verbiage that they use
3 when they are referring to NDMA in their own documents, when
4 they are and looking at evaluating the product itself, and we
5 have had this discussion.

6 We have also tried to limit the burden for Defendants.
7 They have indicated that it would be burdensome and
8 disproportional to prepare a witness to testify about all of
9 the testing that they did in relation to our list over a long
10 period of time.

11 We have offered to them to produce in advance of the
12 deposition specific Bates numbers for specific testing that we
13 might want to question them about so that they can adequately
14 prepare their witness in advance of the deposition.

15 They have indicated that their witnesses could testify
16 to the testing that has been done generally, but they have
17 concerns about the burden and disproportionality of having them
18 testify to specific testing that might have been done ten years
19 ago, 15 years ago, 30 years ago. That is why we offered to
20 help alleviate their burden by identifying the actual testing
21 that we might question in advance of the deposition, and they
22 refused this offer, your Honor.

23 Obviously, the testing that is done -- we have a
24 negligent failure to test claim that has been pled in the
25 complaint, it's in Count 8 for your Honor's convenience, and I

1 know you may not have been able to read the full extent of all
2 of the complaints that have been filed at this point. I know
3 it is the trilogy of Moby Dick, so to speak. So, I understand
4 that, your Honor.

5 In Count 8 we have a negligent failure to test claim
6 against the Defendants, the generic manufacturer Defendants.
7 Within that negligent failure to test claim we have paragraphs
8 that relate directly to specific types of testing that is in
9 this list, the definition, chromatography testing. We also
10 refer to stability testing. All of this is outlined generally
11 within the claims of the negligent failure to test claims, as
12 well as in the stability and degradation and expiration claims.

13 So, we have asked them repeatedly if there was a
14 specific type of testing that they believed was not relevant,
15 to identify it for us so we could have a discussion and they
16 have not been able to do that, your Honor.

17 *THE COURT:* So, let me circle back one second, Ms.
18 Finken. As I understand it, what you are trying to find is,
19 over the course of however many years -- and I realize we are
20 lumping 23 different Defendants into one bucket here and I am
21 going to assume some of these manufacturers have only
22 manufactured the product for a few years, some of them have
23 maybe not manufactured it in the last decade. I recognize
24 there is differentiation within the category here.

25 Essentially, it is my understanding that your theory

1 is they have done testing over time, whichever test it is,
2 which has indicated that Ranitidine can devolve into a
3 carcinogen, a carcinogen can arise from a degradation of the
4 Ranitidine molecule. Am I with you so far?

5 *MS. FINKEN:* Yes.

6 *THE COURT:* That is your theory, that it causes
7 cancer.

8 *MS. FINKEN:* Correct.

9 *THE COURT:* And that they knew it because they were
10 doing testing over time and that testing either did or should
11 have shown them. Okay.

12 So, the testing did show them is your direct evidence
13 of actual knowledge, and now you have a separate failure to
14 test, which is, I guess, they could have and should have done
15 other testing, which they didn't do.

16 *MS. FINKEN:* Correct.

17 *THE COURT:* So, I am assuming the request here is you
18 only want to know what they did do, so then you can compare it
19 and say, well, you didn't do everything else and, therefore,
20 that was your negligent failure to test.

21 Am I with you?

22 *MS. FINKEN:* Your Honor, you are actually making a
23 great point of another concession that we offered to the
24 Defendants, which is, to the extent that they did not do any of
25 the specific types of testing over the course of the time that

1 they had product, they could answer that in an interrogatory
2 answer to expedite the process and alleviate the burden of
3 preparing their witness.

4 This is not necessarily a cross-cutting issue. There
5 are Defendants here that may not have done 50 percent of the
6 types of testing that are on this list, there are Defendants
7 that may not have done any of them, and there are Defendants
8 that may have done all of them.

9 It is variable to each Defendant, which is why we were
10 very specific, it is why we offered up the interrogatory
11 response offers to expedite testimony and burden. We have
12 offered up identifying specific testing ahead of time so that
13 we could have a discussion about it, and we have worked very
14 diligently to try to alleviate the burden, but still get the
15 information that we need from Defendants.

16 *THE COURT:* Putting aside burden for a second, I am
17 going to turn to Mr. Barnes in a second, I want to understand
18 relevance here.

19 The relevance is, it goes to negligent failure to
20 test, to the extent that tests didn't happen, and to the extent
21 tests did happen, the results may have put them on notice that
22 they should have warned the FDA or taken other action with
23 regard to expiration dates or other things that you have
24 alleged.

25 As I recall, you have a negligent failure -- yes,

1 Count 5, failure to warn through the FDA. So you have that,
2 too, right?

3 *MS. FINKEN:* Yes, your Honor, and one of the other
4 items that I want to point out about this testing is, some of
5 this is designed to detect impurities in the product, and the
6 way that the testing was done, that they did over time when the
7 impurities showed up in the chromatograms of the product, there
8 is an argument that they should look into what the impurities
9 were, identifying those impurities as to what type of impurity
10 it was, because NDMA shows up as an impurity on these
11 chromatograms.

12 To the extent that they ignored spikes in the
13 chromatograms because impurities were showing up and never went
14 and did the next step to see what those were, that is obviously
15 something that we would want to ask their witnesses about.

16 I just wanted to make sure that that was clear for
17 your Honor.

18 *THE COURT:* It is. Thank you very much.

19 Mr. Barnes, let me let you respond.

20 *MR. BARNES:* Thank you, your Honor. Thank you,
21 Ms. Finken, for -- just so your Honor is aware, I was not
22 specifically involved with Ms. Finken during the meet and
23 confers. As liaison counsel, I was receiving reports from
24 Ms. Thompson and Mr. Henry.

25 I think we can make some progress perhaps here.

1 If your Honor would hold the Plaintiffs to the
2 representations they have made here today and in their brief,
3 we may not have the issues.

4 Our fundamental concern was that the scope of these
5 questions were impurities. Well, an impurity is anything in a
6 pharmaceutical product that isn't the drug substance. It is a
7 very broad concept. We were trying to get the limitation that
8 the impurities and degradation be limited to the scope of the
9 impurity at issue in this case, which is NDMA. Okay.

10 As I read last night in their opposition, on page two
11 they argue that NDMA is a nitrosamine, a carcinogen, an
12 impurity, a mutagen, and a genotoxin.

13 So, if a document describes NDMA in those terms,
14 obviously that is about NDMA. We will have testimony as to how
15 that -- those terms are analyzed by the industry generally and
16 our clients, but if that -- as long as it is so limited to NDMA
17 and that we get the relevant documents for the deposition
18 and -- you know, then perhaps we don't have the dispute.

19 Asking witnesses about NDMA as a nitrosamine is the
20 issue in the case. It is not like, though, what did you do to
21 look for impurities, or what did you do about nitrosamines
22 generally. To the extent NDMA is a nitrosamine, have at it.

23 We just want the case to be focused on the NDMA issues
24 that are the focus of this MDL. But if it expands to general
25 impurities or the class of chemicals known as nitrosamines and

1 all possible carcinogens, that is way beyond the scope. If it
2 relates to the NDMA that is in this case, then I think we can
3 come to some sort of agreement, I think, amongst the parties.

4 So, I think that is really all I can say. This type
5 of inquiry on testing can get very broad and require us -- some
6 generic may have had a batch that had maybe an impurity,
7 arsenic. We are not chasing shadows here.

8 So, if it is limited to the nitrosamines and
9 genotoxicity, or whatever it is, that intersect with the
10 impurity at issue in this case, which appears to be what they
11 want, then I think we can work through those issues with
12 Ms. Finken.

13 *THE COURT:* Okay. Ms. Finken.

14 *MS. FINKEN:* Your Honor, may I respond?

15 I think the problem here, and we have had these
16 discussions, is that the way that the Defendant asks for these
17 types of impurities cuts across multiple impurities, and it is
18 not like there is just one test for NDMA and one test for
19 another impurity. It cuts across all impurities, and that is
20 the way that they do it.

21 What we have struggled with here is that over a long
22 period of time they have been testing these products for
23 impurities, and impurities were showing up where there was not
24 necessarily a followup being done in terms of identifying what
25 those impurities were. It's our position that over a period of

1 time there were impurities in there that were NDMA and they
2 should have been followed up on, and that was not done.

3 This is why we struggle because it is a little bit of
4 gamesmanship with the wording. We have tried very hard to work
5 with the Defendants to limit the burden of testimony to the
6 span of time that they were testing the products and what
7 specific tests we would want to question them about.

8 But my concern is, by limiting it the way that Mr.
9 Barnes is suggesting, that it is gamesmanship, and it is going
10 to preclude testimony about testing that has been done over
11 time that should have, could have, would have, detected NDMA if
12 they had done the proper followup or the appropriate testing.
13 It may have detected something that they labeled as an unknown
14 impurity, which may have been NDMA.

15 I am talking generally because, obviously, there are
16 23 Defendants, and I haven't looked at all of their testing,
17 nor has all of it been produced at this point. We have been
18 trying to work with the Defendants in terms of burden, in terms
19 of scope; they have been unwilling to work with us.

20 We are not willing to limit the terminology to testing
21 or questioning just specifically about NDMA because, as a
22 practical matter, that is not how they test these products.
23 They don't test it that way.

24 *THE COURT:* Okay, I hear you.

25 *MR. HENRY:* Your Honor, Terry Henry for Apotex. Could

1 I have one brief moment to respond to Ms. Finken?

2 *THE COURT:* Sure.

3 *MR. HENRY:* Your Honor, I wanted to address a couple
4 of issues. The first is the proposal by the Plaintiffs that
5 they identify documents five days in advance of a deposition in
6 order for us to answer questions and reduce the burden on our
7 witness. We actually thought that that was a workable
8 solution. The problem was, on the back end the Plaintiffs did
9 not agree to not ask questions about the other 28 odd tests
10 that were in the list.

11 Similarly, we had thought we had worked out an
12 agreement on the interrogatory, so the Plaintiffs list the
13 tests, we answer that with an interrogatory saying which tests
14 we did on Ranitidine. But the Plaintiffs did not agree that
15 that would relieve us of the obligation of preparing a witness
16 to testify about the other 26 or 27 tests that we didn't do.

17 So, for us on our side, even though we had some of
18 these proposals on the table, it did not reduce the burden on
19 preparing witnesses to present testimony at the 30(b)(6)
20 deposition when they are speaking on behalf of the entire
21 corporation.

22 Now, we do understand the Plaintiffs' concern that if
23 they show a witness a chromatograph that has a stray peak as
24 unidentified, Plaintiffs' concern is that a Defendant is going
25 to object and say that is not NDMA and I don't have to answer

1 any questions about it. I think -- I understand that concern.

2 I think it is a stretch to say we'd have Defendants
3 playing those games at a deposition because there is a PTO 32
4 process that the Plaintiff can seek a remedy for that. I also
5 think that there is a way that we can resolve those issues up
6 front, particularly if the Plaintiff is presenting the
7 documents before the deposition so that there could be a meet
8 and confer process.

9 That is all I have to say on that, your Honor.

10 *THE COURT:* Thank you. Let me start with this. As
11 far as I am concerned, you all can negotiate any time you want
12 to, before or after, but when you come to me, I am not here to
13 negotiate with you. I am here to rule on the issue that you
14 have framed for me.

15 You all can talk all you want. I am going to rule on
16 the legal issue you present me, and your time to negotiate on
17 that issue is over. I am going to rule. First thing.

18 Second thing, I hear you, Mr. Henry, but I continue to
19 be baffled by the argument that there is some burden to prepare
20 a witness to say, we never did that test. What is the burden
21 to prepare a witness to say, we never did that test?

22 *MR. HENRY:* Your Honor, from my perspective, there is
23 going to be more than one of those questions. There is going
24 to be a series of questions in which the Plaintiff will attempt
25 to establish that because the Defendant did not adequately

1 evaluate, or purchase the equipment, or properly calibrate some
2 other piece of equipment, that there is some form of negligence
3 there. Right?

4 So, rather than testifying about the process of
5 selecting the test that they did do, there will be questions
6 about the 26, 27 tests that the Defendant didn't do, and I have
7 a burden to prepare my witness to understand what those tests
8 are, and what, if anything, the company did in order to select
9 between those tests. That is the burden, your Honor.

10 *THE COURT:* Okay. Again, I think if the question is
11 simply, did you do this test, there is no burden to answer
12 that. If the question is, why didn't you do those tests, that
13 may be a different issue, but that is not the issue before me.

14 I am going to overrule the objection and the request
15 for protective order. I find the requested evidence, for the
16 reasons Ms. Finken has articulated, is relevant to the claim,
17 it is proportional to the needs of the case.

18 I think the -- my sense of it is that the Defendants
19 are giving this a hyper technical reading, that in the real
20 world, I don't think Ms. Finken or Mr. McGlamry or Ms. Luhana,
21 or whoever is going to take this deposition, is really going to
22 waste their seven hours, that they -- one time only seven hour
23 deposition probing all these aspects of did you have an
24 impurity caused by somebody dropping their Dippin' Dots into
25 the vat.

1 I just don't see it, I don't see the undue burden
2 here, so I will overrule the request for a protective order on
3 that issue.

4 Does that also subsume within it, Mr. Barnes, the next
5 issue in your memo here, which is that the notice should be
6 limited to NDMA, not all nitrosamines or impurities, that I
7 just merge B and C?

8 *MR. BARNES:* Let me make sure I understand, your
9 Honor. As I am hearing your ruling, that we would -- the
10 testing that we did, whatever it is, the testing that was done
11 would be limited to those tests that were done to assess the
12 degradation of the Ranitidine and the products of the
13 degradation, and we want to limit it to NDMA and the products
14 of, you know, the degradation process, and not just generally
15 nitrosamines and other impurities. We want to focus the case
16 on the tests that were designed to look at the degradation and
17 then the formation of Ranitidine, I mean NDMA.

18 As long as it is confined to the questions of the
19 testing that was performed on the Ranitidine molecule to see,
20 you know, how stable it was, and they -- Ms. Finken will ask,
21 well, you didn't go far enough once you did this test. I think
22 the generics need to respond, we went as far as USP requires
23 and the evidence required us to, and that would be a question
24 for experts.

25 As long as it is not a wide-ranging discussion of

1 impurities generally, I think we can get through the deposition
2 without a fight.

3 *THE COURT:* Ms. Finken, is that different from what I
4 have already ruled on?

5 *MS. FINKEN:* No, your Honor, it is not different and
6 the reason why it is not different is that the terminology
7 NDMA, nitrosamine, impurity, carcinogen is used in conjunction
8 with the definition of testing in the definition. That is
9 where the terminology comes up within the definition of
10 testing, and it all overlaps.

11 So, I do not believe that it is a separate issue as it
12 is all used in conjunction with the testing that we just
13 discussed.

14 *THE COURT:* If I understand your argument from before,
15 where those words come from is from tests -- discovery you have
16 received where one or more of these generic manufacturers has
17 used that terminology to describe a degraded NDMA molecule. Is
18 that correct?

19 *MS. FINKEN:* Correct. Your Honor, we have attached
20 some of them as exhibits to the motion. They refer to NDMA as
21 a nitrosamine. They refer to it as an impurity, a genotoxic
22 impurity, and a carcinogen in their own documents.

23 *THE COURT:* I just --

24 *MR. BARNES:* Let me make it clear, as long as it is in
25 the context of NDMA -- I am sorry.

1 *THE COURT:* Go ahead, Mr. Barnes.

2 *MR. BARNES:* I apologize. As long as the -- if there
3 is a paragraph where they talk about the nitrosamine, NDMA, and
4 its carcinogenic potential, that is NDMA and it can be
5 described in that way, then we would not have a problem. But
6 if it is all nitrosamines, well, the pathway for all
7 nitrosamines is not this case. There are all sorts of ways
8 nitrosamines can be formed. It is a different kettle of fish.

9 *THE COURT:* Understood. This is exactly why I don't
10 like to rule on these things in advance.

11 The specific question that Ms. Finken asks to the
12 manufacturer who has used the phrase "impurity" in their prior
13 testing will be very different, or may be in a different
14 context, or may require a different ruling than if she asks the
15 same question to a manufacturer who has never used that term in
16 their own documentation.

17 So, as to this, I am going to not at this time grant a
18 protective order. I have given you the guidance I believe I
19 need to give you. I think there is sufficient room here for
20 the deposition to go forward, and if a Defendant believes
21 either that they don't need to or don't want to prep a witness
22 because they think this is an improper area of questioning,
23 Ms. Finken will ask the questions, you will instruct the
24 witness not to answer the questions, and then on a full record
25 I will rule on that.

1 This is getting too granular for anything I am
2 comfortable dealing with in advance. I will let you ask the
3 questions, and lodge whatever objections you want to lodge, and
4 we will go from there.

5 I will make very clear to the responding parties, if
6 your intention is to instruct your witness not to answer areas
7 of questioning you can choose not to prep your witness to
8 answer those questions. You proceed at your own risk, because
9 if I determine that they should have been prepared to answer
10 the question, there will be a second deposition, you will pay
11 for it, and we will go from there. That's just how this has to
12 work.

13 Let's go to the last issue because I want to get Mr.
14 Barnes out of here by four o'clock.

15 *MS. THOMPSON:* Your Honor, Sara Thompson for Defendant
16 Teva.

17 I just wanted to point out two things. Number one,
18 this is not limited to testing, the manufacturing notice. This
19 definition related to impurities, carcinogens, expanding beyond
20 NDMA is in two other sections of the manufacturing notice. So,
21 I just want to make sure that we are being clear because it is
22 different in the context of testing than the two other contexts
23 where it is brought up, which is quality assurance and quality
24 control activities. It is in multiple subparts there.

25 It is also in multiple subparts related to compliance

1 with current good manufacturing practices, or CGMPs. We
2 haven't talked about that yet, we have only talked about it in
3 the context of testing.

4 Before your Honor makes a ruling that may be held by
5 Plaintiffs or by the Court as to other categories, I wanted to
6 make sure we talked about it in that context because it is a
7 little bit different.

8 *THE COURT:* Is there anything substantively you want
9 to be heard on on that?

10 *MS. THOMPSON:* Yes, your Honor. I think the main
11 issue here is that NDMA or nitrosamines are the focus here as
12 opposed to all other types of carcinogens, impurities,
13 genotoxic impurities, et cetera. That is the scope of this
14 MDL, that is what the JPML assigned to this Court.

15 If we are talking about quality control activities
16 designed to detect any impurity, that will dramatically
17 increase the scope of the depositions, potentially increase the
18 number of witnesses who have to cover those topics. Things
19 that could be counted as impurities include irrelevant things
20 like microbial contamination that have no place here in this
21 MDL.

22 I just wanted to make sure we didn't move off of that
23 topic, understanding that it is not limited to testing in this
24 notice and we didn't limit it to testing.

25 *THE COURT:* Understood. I am going to adhere to my

1 ruling because my ruling is not necessarily that they are
2 allowed to ask you about those things. My ruling is simply I
3 cannot judge that today. You, as the party deponent, can deal
4 with it accordingly.

5 I will rule on it when I have a clear record and I can
6 see it in context. So, that is my ruling to that as well,
7 which is essentially a nonruling. My ruling is you don't get a
8 protective order today, and we will move forward from there.

9 The last issue, then, on the manufacturers, I want to
10 finish this up and then we will take a ten minute break, is
11 time limitations and not limited to activities directed at the
12 U.S. market.

13 Mr. Yoo, I noticed you turned on your camera. Is
14 there something you want to be heard on before I move on?

15 MR. YOO: I will wait, your Honor. I thought I could
16 be helpful, but based on your last comment, I will just wait
17 until you get to the next motion, your Honor.

18 THE COURT: Very well. Thank you, Mr. Yoo.

19 MR. BARNES: To the extent we are talking about --

20 THE COURT: You have to identify yourself, Mr. Barnes.

21 MR. BARNES: I'm sorry. Richard Barnes.

22 What is the next topic you wanted to address?

23 THE COURT: I'm going down your memo here. It's topic
24 D on page three of your memo.

25 MR. BARNES: Time limitations, is that Ms. Thompson's

1 subject? That cuts across several notices so perhaps
2 Ms. Thompson can handle that. Mr. Yoo is handling foreign --
3 non U.S. issues. I think those are the two points you made.
4 They cut across several notices and I think Ms. Thompson
5 handles the timing, and Mr. Yoo will cover the foreign
6 regulatory issues.

7 *MS. FINKEN:* Your Honor, may I address the timing for
8 just a moment?

9 *THE COURT:* Hold on, stop, stop. Who are you?

10 *MS. FINKEN:* Tracy Finken on behalf of Plaintiffs.
11 Sorry, Ms. Stipes.

12 May I address the timing part of this for a second?

13 *THE COURT:* Yes. Go ahead.

14 *MS. FINKEN:* I just wanted to bring this up because we
15 discussed this over the weekend, and we discussed the fact that
16 the timing aspect is very variable as it relates to each
17 generic manufacturer. They all had these products at very
18 different times and this is not really a cross-cutting issue
19 that should apply to all generic manufacturers.

20 It is something that we should address as it pertains
21 to each individual generic manufacturer when we do our meet and
22 confers with each in relation to the deposition, and is not
23 appropriate to do as a cross-cutting issue, your Honor.

24 *THE COURT:* I understand your position. Let me hear
25 from Ms. Thompson.

1 MS. THOMPSON: Thank you, your Honor, Sara Thompson
2 for the Teva Defendants.

3 While Ms. Finken is correct that she did propose that
4 we could deal with this on an individual Defendant basis, there
5 is one cross-cutting issue, and that is that none of the
6 notices have any time limitation or relevant date range at all
7 specified within them.

8 As your Honor may remember, I am sure it feels like a
9 lifetime ago, at the personal jurisdiction discovery hearing
10 your Honor asked questions about this, what should be the
11 relevant time period, and ultimately made a ruling based on the
12 length of involvement of each of the Defendants who are going
13 to have to answer that discovery of how far back it would go.

14 Even though some of those Defendants went back as far
15 as 1997, which was the first date that Ranitidine was approved
16 for sale in the U.S., your Honor ruled that four years was the
17 appropriate time range, in part based on the average length of
18 Statute of Limitations state by state was shorter than four
19 years in most instances, and four years was kind of the outer
20 limit.

21 We actually had proposed to your Honor a ten-year look
22 back, which is broader than the four years that your Honor
23 ruled in the personal jurisdiction context. The reason was
24 because we recognize that some Defendants, my clients included,
25 stopped selling Ranitidine years before this litigation was

1 filed and years before the events that occurred in 2019 that
2 led to this litigation.

3 So as a result of that, we proposed going back ten
4 years for two reasons. Number one, to ensure that we were
5 actually encompassing more of the relevant time period; and
6 number two, because most of these Defendants are going to have
7 to educate a witness through documents.

8 A lot of us have a really long history. My clients go
9 back as far as 1997. A lot of the generics acquired companies
10 that had previously made Ranitidine, so there is no one left
11 who knows that history personally. A lot of these companies
12 are off the market now, including my client.

13 In each of those instances, you don't have necessarily
14 someone with personal knowledge, so you have to inform it
15 through documents, and document retention, unfortunately, only
16 goes back a certain amount of time. So, that was intended to
17 target it to when we would actually potentially have documents
18 that could inform the testimony.

19 Setting aside what your Honor raised at the
20 in-chambers conference, which was the somewhat dubious value of
21 having a witness read from very old documents who doesn't have
22 any additional knowledge to add.

23 That is why we proposed the ten years. The Plaintiffs
24 have rejected that. This proposal to do it on a
25 Defendant-by-Defendant basis was incorporated into our briefing

1 as something that we would find acceptable, but we would like
2 the Court's guidance on whether or not that is going to go back
3 to the very beginning of when a Defendant ever had involvement,
4 particularly if they may not have witnesses available with
5 knowledge, documents to inform the testimony, because that
6 impacts the burden and the proportionality analysis.

7 *THE COURT:* Can I ask you, your ten-year proposal --
8 again, I am not going to negotiate this with you, I just want
9 to understand it.

10 Was it ten years from today or ten years from the last
11 manufacture? If your client stopped manufacturing this in
12 2005, are you offering '95 to 2005, or are you offering 2011 to
13 2021, in which case you have nothing?

14 *MS. THOMPSON:* Sara Thompson again, your Honor. We
15 proposed January 1st, 2010, until the filing date of this MDL,
16 which was February 2020. We thought that was a reasonable time
17 period, that we go back ten years from when the MDL was formed.

18 *THE COURT:* I understand that proposal.

19 What is the legal objection that you are making to the
20 notice that I need to rule on today?

21 *MS. THOMPSON:* There are two issues, your Honor.
22 Number one is that there is just a lack of a relevant time
23 period at all. There is no time limitation at all as the
24 notices are presently drafted. We raised this issue
25 previously, this didn't come up recently. This was included in

1 objections that were served to a prior iteration of this
2 notice.

3 There are numerous cases cited in our briefing where
4 Courts have granted protective orders where there was no date
5 range specified at all, or where the date range would have
6 potentially implicated decades of history that was unlikely to
7 be proportional to the needs of the case.

8 Issue number one is just that there is no date range.
9 Issue number two is that if there is going to be a
10 Defendant-by-Defendant date range, we would like some thought
11 to how we balance the burdens and the proportionality,
12 particularly for those Defendants who have long history, who
13 acquired other entities who had ceased manufacture, and those
14 Defendants who may not still have documents from the older time
15 period.

16 *THE COURT:* I understand your position. Let me ask
17 Ms. Finken.

18 I assume your position is that the date range is
19 whatever period of time you manufactured the stuff.

20 *MS. FINKEN:* Correct, your Honor. I would just like
21 to point out that all of the Defendants' products are off the
22 market right now because it is a globally recalled product that
23 Defendants admit contain a carcinogen.

24 We have thousands of people that have registered
25 claims in the registry who allege that they have taken generic

1 manufactured products that date back to the time that they
2 began manufacturing it, and we should be able to take discovery
3 as it relates to that timeframe.

4 We have individuals with cancer that used the products
5 when Teva marketed it, we have it when Perrigo marketed it, we
6 have it when Dr. Reddy's marketed it. They bought it, they
7 consumed it, they have cancer, and it is a globally recalled
8 product that contains, admittedly by Defendants, a known
9 carcinogen.

10 So, we would suggest that the timeframe should be the
11 relevant timeframe that they had the product, they manufactured
12 it, and they marketed it in the U.S.

13 *THE COURT:* What about a response to their burden
14 argument? Ms. Thompson said she represents Teva, and Teva
15 started making this drug -- when, Ms. Thompson, in 1995?

16 *MS. THOMPSON:* Yes, your Honor, that either we made or
17 an acquired entity made, and it goes back as far as 1997.

18 *MS. FINKEN:* In terms of burden, your Honor, this is
19 something that we have discussed at length with the Defendants,
20 which is why, if you notice -- I don't know if you can tell
21 from the notices that Defendants attached to their motions
22 because they are not the operative notices that have been
23 through the meet and confer process, the ones that we provided
24 are that have been through several iterations of redlines over
25 the 30 hours I spent meeting and conferring over these.

1 But with that being said, if you notice, in our notice
2 we provided the opportunity for certain areas of the notice of
3 deposition that the Defendants can answer by interrogatory
4 responses so that we can expedite and alleviate the burden and
5 the testimony in this case. The witness could rely on the
6 interrogatory responses for purposes of certain questions, for
7 foundational purposes and whatnot, and we have worked very
8 diligently with them to try to help assist with this timeframe.

9 This is not something that we have run into an
10 objection with other brand Defendants who have had the product
11 as long, if not longer, than these generic Defendants on the
12 market.

13 From our perspective, we have worked diligently to try
14 to alleviate the burden. It is all relevant to our clients'
15 claims who took the product over the life span that they
16 marketed and manufactured it, and we think it is critical and
17 highly relevant to the case.

18 *THE COURT:* I have your the notice that you submitted
19 to me. Where is the part about they can opt to respond
20 by interrogatory?

21 *MS. FINKEN:* Your Honor, at the top, I believe it's at
22 the top of the -- I might have to phone a friend.

23 *MS. THOMPSON:* Your Honor, it is in the instructions.
24 Sara Thompson.

25 *MS. FINKEN:* It is in the instructions and it provides

1 certain questions that are acceptable for us to be answered by
2 interrogatory.

3 *THE COURT:* I see that.

4 *MS. FINKEN:* This was agreed to by the parties. It is
5 in PTO 60, we have addressed it.

6 *THE COURT:* Okay. I see that. All right.

7 At this point, again, I am not going to rule -- I am
8 not going to unilaterally impose any time limits because I have
9 no evidentiary basis from the Defendants to impose any sort of
10 time limit. I don't know whether it is really hard or really
11 easy for Dr. Reddy or Teva or Strides, or whoever it is, to
12 retrieve documents or not. I don't know.

13 I have no record on which to rule, so I am going to
14 deny the motion for protective order, again, without prejudice
15 if you all want to continue to talk.

16 It seems like the Plaintiffs have made a reasonable
17 proposal to try to limit the burden. If on an individualized
18 basis a particular manufacturer feels that they have an
19 evidentiary basis to object, you can invoke PTO 32 on behalf of
20 that individual Defendant, but I don't think I can make a
21 blanket -- and I will decline to make a blanket ruling on a
22 time limit or anything like that.

23 I do agree that it is very individualized. If I say
24 ten years back and Teva did a lot of testing in the '90's and
25 early 2000's, and then they just stopped testing, then the

1 Plaintiffs don't get evidence that Plaintiffs need. On the
2 other hand, the Plaintiffs may get a whole lot of cumulative
3 testing that they don't need, but I can't rule on that as I sit
4 here today.

5 I am denying the motion for protective order, but
6 without prejudice to an individual Defendant raising a PTO 32
7 objection, and you can submit your evidence and I will rule
8 based on the evidence.

9 I think those are all the issues --

10 *MS. THOMPSON:* Sara Thompson for Teva. While Mr.
11 Barnes said Mr. Yoo is going to address one aspect of the U.S.
12 versus global, we also raised an issue here specifically with
13 respect to the storage and transportation and manufacturing
14 notice that is a little bit different than just the regulatory
15 aspect. I don't know if you want to do that now or if you want
16 to wait.

17 *THE COURT:* Sure, go ahead.

18 *MS. THOMPSON:* One of the things that we raised, your
19 Honor, in our objection specifically to the storage and
20 transportation notice which, as I mentioned earlier, was the
21 first notice that was served by Plaintiffs and where we have
22 done the most meeting and conferring. Ms. Finken mentioned 30
23 hours. I haven't added it up for my bills, but having entered
24 all of my time for February last night, I know it was a lot.
25 Mr. Henry and I were on a lot of calls about this notice and

1 the other three notices.

2 This was an issue that, at the risk of confusing
3 things, we called a global issue because it applied to all
4 three notices, but it is the question of whether or not we are
5 focused on products made for the U.S. market or if we are
6 focused on Ranitidine made for any market.

7 This is particularly important in the generics space
8 because we have a lot of generics here who made product not
9 only for the U.S., but for other countries or other regions.

10 *THE COURT:* I'm sorry, Ms. Thompson, let me stop you.
11 I recall this issue. Let's just put this aside. I want to
12 deal with this when we deal with the storage and transport
13 issues just because in my thought processes that is where I had
14 pigeonholed it.

15 *MS. THOMPSON:* That's fine, your Honor. I just wanted
16 to make sure because you asked were there any other issues for
17 the manufacturing and this does apply there, too.

18 *THE COURT:* No, I appreciate that. Mr. Yoo, I think
19 you had an issue with regard to the manufacturing aspect. Is
20 that now or is that a later issue?

21 *MR. YOO:* Your Honor, I am supposed to argue the
22 motion as it relates to pharmacovigilance, but I think these
23 cross-cutting issues affect all three of the motions. Some of
24 these issues have already been covered by your Honor's ruling.

25 *THE COURT:* I am using your three memos or your three

1 motions as my agenda, so if the topic that you plan to argue,
2 Mr. Yoo, is in the pharmacovigilance memo, we will get to that
3 when I get to the pharmacovigilance memo.

4 Right now, I am just working off of the Defendants'
5 motion regarding manufacturers. There were four topics, A, B,
6 C, D. I just want to make sure, not waiving any objections you
7 have to the rulings I have made, I will turn to Mr. Barnes.

8 Have I at least ruled on the issues that you believe
9 you raised in A, B, C, D of your motion?

10 *MR. BARNES:* Your Honor, I believe that we raised
11 issues about the solvents. In the interest of time, my sense
12 is that you would have the same ruling on the same rationales
13 that you have used to dispose of the other issues, so we don't
14 need to talk about solvents.

15 I believe the rationale you applied would suggest that
16 they would be allowed to inquire as to that on the same
17 rationale as you came down on testing.

18 *THE COURT:* That is correct.

19 *MR. BARNES:* So, I think, then, if that -- I think we
20 are in agreement that that would be the outcome. I would say
21 the manufacturing issues that we raised in our motion have been
22 dealt with, sir.

23 *THE COURT:* Okay. Again, you are not waiving any
24 objections you have, and you are preserving all objections to
25 my rulings if you want to raise those issues with Judge

1 Rosenberg. I just want to make sure I have ruled on everything
2 you wanted ruled on.

3 Here is what I'd like to do. It is 3:40. Let's take
4 a recess until 3:50. When we come back I would like to take up
5 the storage and transport issues. Are you arguing those,
6 Ms. Finken? I know Ms. Goldenberg is arguing something.

7 *MS. FINKEN:* Yes, your Honor, that's me.

8 *THE COURT:* That one seems to me, at least from the
9 memo I have read, compared to what we just did, shorter. I
10 would like to get through that quickly and then we'll go to the
11 pharmacovigilance immediately after that.

12 Let's take a ten-minute recess and come back at 3:50.
13 We will be in recess for ten minutes.

14 *MS. FINKEN:* Thank you.

15 *(Thereupon, a short recess was taken.)*

16 *THE COURT:* Let's go back on the record. Good
17 afternoon, everyone. Before we took the break, I said we would
18 take up when we came back the storage and transportation
19 motion.

20 Ms. Thompson, I understand we were going to use this
21 as the vehicle to talk about the foreign manufacturer, domestic
22 manufacturer issue. Are you going to address that or is Mr.
23 Yoo going to address that?

24 *MS. THOMPSON:* Sara Thompson for Teva. I am going to
25 address it more on the product, where it was intended to be or

1 where it actually was sold. I believe Mr. Yoo is going to
2 address it in the context of regulatory agencies.

3 *THE COURT:* All right. Very good. We will do that.
4 I am going to use, so everyone understands, the Defense's
5 motion as my agenda item.

6 I reviewed the motion, I reviewed the response, and I
7 reviewed the chart, and it wasn't clear to me that there was
8 anything left at issue. At least Ms. Finken's response seemed
9 to be that we have resolved everything.

10 Ms. Thompson, let me turn to you. What do you believe
11 to still be at issue as it relates to the issues framed in the
12 storage and transport memo and the chart that was attached to
13 it?

14 *MS. THOMPSON:* Thank you, your Honor. Sara Thompson
15 again for Teva. I think the only issue remaining is this ex
16 U.S. versus U.S. product issue. We noted here that we
17 incorporated the arguments that we had made so I think this is
18 the only one left as to this notice that we haven't already
19 discussed.

20 There were also individual objections, but we did not
21 brief all of those, as your Honor noted, we are focusing on
22 what is actually in the submission itself.

23 *THE COURT:* Very good. Although I will tell you, my
24 reading of even the ones you didn't fully brief, Ms. Finken's
25 responses were either it is moot or it is no longer in the

1 notice.

2 I will let you all work that out between yourselves.
3 It seemed to me there may not be as much to fight about as it
4 might have looked like in the first instance.

5 Let's talk about the foreign versus domestic issue.
6 Ms. Thompson, let me let you frame the issue from your
7 perspective.

8 *MS. THOMPSON:* Sure. I think that the most important
9 thing here to keep in mind is what the claims in the amended
10 master personal injury complaint are directed to.

11 There are storage and transport condition claims, it
12 starts with Count 10, and they go through 50 states, but they
13 are all focused on product that was sold and used in the U.S.,
14 and they are focused on how that product at every step of the
15 way arrived, was stored here, was distributed here.

16 From the API sourcing, the active pharmaceutical
17 ingredient, how that got here, where it was stored when it
18 arrived here before it was used to manufacture the product,
19 where the manufactured product was stored either here or
20 manufactured overseas and then shipped here, and then where
21 finished drug product was distributed. That is the focus for
22 all of these claims, it is on product that ultimately was
23 distributed and used in the United States.

24 So, we have asked for the limitation that the
25 Ranitidine containing products be limited to those that were

1 sold and distributed in the U.S. market, that were imported or
2 manufactured for the U.S. market as opposed to globally. This
3 is important because many of the manufacturers, including Teva
4 -- we are by far and away not the only one -- made product for
5 the U.S. and for other markets. We may have made it at
6 different places, that is definitely true for Teva.

7 There is no overlap whatsoever between our suppliers
8 and our manufacturing facilities for non U.S. markets and for
9 U.S. markets. We sourced our API from different entities for
10 the most part. There is one exception.

11 So, we don't have commonality of issues that are
12 focused on in this notice if we expand it beyond the U.S., so
13 it literally doubles, or even triples, or quadruples the
14 burden. It potentially requires a different witness as part of
15 preparing to disclose deposition dates.

16 One of the things that we looked into was who would be
17 the right person to speak about API sourcing Ranitidine
18 containing products. We learned it is a different person for
19 the U.S. versus the rest of the world. If we have to speak to
20 the entire world, that is multiple witnesses, and it's
21 different people using different documents, using different
22 systems, meeting different standards.

23 So, this is a really important limitation that we
24 thought would be noncontroversial, but whenever we have tried
25 to raise this we have been told that because this was a product

1 that was sold globally, that Plaintiffs will refuse to limit it
2 to manufactured for the U.S. market.

3 However, their submission does seem to suggest that
4 that is Plaintiffs' position with respect to this notice
5 because there is a statement in there about some of this
6 product is made outside the U.S. but then is imported into the
7 U.S.

8 We are not suggesting that if it is merely made
9 outside the U.S. that it is somehow not relevant or that it
10 should be not relevant. We are saying if it is not made for
11 the U.S., if we are talking about product that never came to
12 the United States, that should be outside the scope of the
13 notice.

14 All along when we have been negotiating this we have
15 been focusing on who did we supply -- or who did we source our
16 API from, who were our third-party manufacturers, where was it
17 stored when it came into the United States.

18 There was never an understanding, I think, among
19 either side until very recently that this was intended to be a
20 global scope of storage and transport. That is why we are
21 raising it here, but we raise it with respect to the other
22 notices as well because it is also an issue for manufacturing.

23 The products are made at a different place if they are
24 for non U.S. markets. The products are likely also stored then
25 at a different place if they are made for non U.S. markets. If

1 they are made elsewhere, they are probably stored elsewhere.

2 They are sourced from different suppliers. The
3 policies and procedures are likely not the same, then, when you
4 are dealing with product that is made at one plant versus
5 another or in one country for that country's standards.

6 So, these are the reasons why this really has the
7 potential, if we do not limit it to product sold in the United
8 States, which is the focus of the amended master personal
9 injury complaint, it is the focus of this MDL, products sold in
10 the United States.

11 *THE COURT:* Let me, again, make sure I understand your
12 point.

13 There is an evolutionary life cycle to each of these
14 pharmaceuticals, right? Let's take it backwards. It is sold
15 and consumed by somebody in the United States who the
16 Plaintiffs allege got cancer. If we trace it backwards, it had
17 to get to that person, it had to be sold to that person, it had
18 to be manufactured somewhere, the manufacturer had to get its
19 basic ingredients, its API somewhere, et cetera.

20 If I understand you, you are not objecting to the
21 Plaintiffs getting discovery of that life cycle. As long as
22 the product ended up in the body of a human being in the United
23 States, you are okay tracing it all the way back to the source.

24 Your objection is the opposite, which is if it ended
25 up in the body of somebody outside the United States the supply

1 chain and the manufacturing chain and everything else should
2 not be. Am I understanding you correctly?

3 *MS. THOMPSON:* Yes, your Honor. I think one thing
4 that is important is some of these may have been made at a
5 facility that made it both for the U.S. and for other
6 countries. We are not talking about eliminating that as a
7 relevant issue. We just want to focus on what actually
8 happened with product that ended up in the United States.

9 If we can just carve out product that never touched
10 the United States, that was never intended for here, that never
11 traveled through here, this will dramatically decrease the
12 burden of putting up witnesses.

13 And if we have to put up witnesses on those other
14 topics it is going to expand the number of depositions, the
15 burden to get ready, the time that is going to be required, and
16 it will be of no benefit to the actual claims in this case that
17 are related to storage and transportation of product within the
18 United States according to the Plaintiffs' own pleading for all
19 50 states, storage and transport claims.

20 *THE COURT:* Got it. I understand. Let me turn to
21 Ms. Finken and let her respond to that.

22 *MS. FINKEN:* Yes, your Honor. I think you sensed my
23 confusion in our response to the motion because I thought we
24 had an agreement on this storage and transport notice of
25 deposition. I don't think that there is a dispute, to be

1 honest with you.

2 Our storage and transport notice, while -- if what
3 Ms. Thompson is saying is correct, that they are not going to
4 dispute providing witness testimony and documents in relation
5 to foreign manufacturing of U.S. product, and storage and
6 transport of U.S. product that is made overseas and how it gets
7 over here and where it is stored over there, it does not sound
8 like we have a dispute. That is what we are seeking.

9 *THE COURT:* My question to you was going to be: Do we
10 have any Plaintiff in this case who didn't consume their
11 Ranitidine in the United States?

12 *MS. FINKEN:* To be honest with you, your Honor, I do
13 not know. If we do, it would probably be minimal. That is not
14 what we are seeking right now.

15 We are seeking storage and transport, whether it is
16 overseas or whether it is in the U.S., based upon the U.S.
17 products that come here, because the bulk of it is manufactured
18 overseas. I think Ms. Thompson will admit to that and that is
19 something that is highly relevant in terms of the storage and
20 transport claim.

21 As long as that is their position, that they are not
22 going to limit that, I think that we probably don't have a
23 dispute.

24 *THE COURT:* Ms. Thompson, do we have an agreement?

25 *MS. THOMPSON:* Sara Thompson again for Teva.

1 Your Honor, I think the thing that we propose, that I
2 think makes sense, is to define in each of the notices "your
3 RCPs" as your products that were made or sold in the United
4 States. That is what we were taking about, and we have that
5 definition that we had previously proposed to Plaintiffs, but
6 we had not reached agreement on it. That would focus it
7 appropriately on the products that were actually used in the
8 United States by these Plaintiffs.

9 *THE COURT:* Okay. Here is what I am going to do. I
10 will leave it to you two to wordsmith how you want to deal with
11 this.

12 My ruling would be that, to the extent the 30(b)(6)
13 notice could be interpreted to require testimony relating to
14 the manufacture, distribution, storage, transport, et cetera,
15 the life cycle of pharmaceuticals that were not consumed in the
16 United States, I would exclude that from the 30(b)(6) notice.

17 You two can redraft it however you want to. I think
18 those are the meeting of the minds that you two have reached
19 and I will leave it to you to write it up, but that's my
20 ruling.

21 The generic Defendants do not have to produce a
22 witness who can testify about the life cycle of drugs that were
23 sold in Japan, in Israel, in Great Britain, and everywhere
24 else, only in the U.S.

25 Does that resolve transport and storage? Have we set

1 a world record in resolving that?

2 *MS. THOMPSON:* I believe so, your Honor. Those were
3 the main issues that we had briefed.

4 *THE COURT:* Okay. Ms. Thompson is going to retire
5 undefeated. Then I think we move to PV, to pharmacovigilance.
6 I practiced saying that so I would not fall behind Judge
7 Rosenberg.

8 Mr. Yoo and Ms. Goldenberg, good afternoon.

9 *MR. YOO:* Good afternoon, your Honor. Thomas Yoo for
10 the generic Defendants.

11 *THE COURT:* Good afternoon.

12 *MR. YOO:* We are on a roll, I will try not to mess it
13 up, your Honor.

14 I didn't want to jump in earlier because Ms. Finken
15 was a little bit out numbered, but she actually did pretty
16 well. Maybe we should have brought more people on our side.

17 You made a comment that I thought was an important
18 comment. You said that you felt as if the Defendants were
19 doing a hyper technical reading of the deposition notice. If
20 that is the case, your Honor, I think it is because the way the
21 30(b)(6) notices were written by the Plaintiffs, it was our
22 concern that there were too many definitions and statements
23 that were just out there untethered to a context for this case.

24 If I am hearing your Honor's comments and Ms. Finken's
25 comments today, if I am understanding them correctly, I think

1 we've got the necessary context to allay a lot of those
2 concerns.

3 For example, I think, from our perspective, it would
4 have been much easier for us to understand what the Plaintiffs
5 wanted if they had asked for a witness regarding, for example,
6 the testing that we did. We don't disagree that they get a
7 witness to talk about the testing that each of us did do, but
8 they didn't ask it that way. They said, give us a witness on
9 this type of chromatography and this type of analysis and that
10 type of analysis in a vacuum.

11 It was almost like we got a list of a hundred expert
12 topics and we had to go find witnesses to cover those topics
13 whether they had anything to do with what we did with regard to
14 Ranitidine.

15 So, if the context is it relates to what we did with
16 our product that was used by someone in the United States that
17 makes eminent sense.

18 So, I say that because I think it is going to take
19 care of some of the issues that I came armed with. We probably
20 don't need to get into those in as much detail, but one of the
21 things that we put in our motion, as your Honor can see, is,
22 the Plaintiffs ask for pharmacovigilance witnesses to talk
23 about a variety of topics, again, as written in a vacuum,
24 carcinogens, toxic impurities, nitrosamines.

25 Our feeling was this MDL expressly is about NDMA and

1 Ranitidine and allegations that we withheld safety information
2 or risk information about NDMA in Ranitidine in the United
3 States. If that is the understanding of the context, then we
4 are fine.

5 If I am understanding Ms. Finken's comments earlier,
6 they saw some documents from the Defendants where some of the
7 Defendants used NDMA interchangeably with nitrosamine or
8 carcinogen or impurity. I get that.

9 If we are still talking about NDMA, then certainly
10 they can ask about our use of the term nitrosamine as opposed
11 to NDMA.

12 If, on the other hand, if they want a witness to give
13 expert testimony about carcinogens, the hundreds of carcinogens
14 listed by EPA and other agencies, then that's a problem, but I
15 don't think, from what I am hearing today, that we are going to
16 actually run into that when the depositions occur.

17 I think the only remaining issue as far as
18 pharmacovigilance is concerned, your Honor --

19 *THE COURT:* Hold on. Okay.

20 Mr. Yoo, what is the issue that you think we do need
21 to address?

22 Before we get to that, let me just say, my hope had
23 been -- my assumption had been that those sorts of
24 clarifications had been worked out during the meet and
25 conferral process, because we have all been there. When you

1 draft a document request and deposition notice you only have
2 the words that you have, and those words sometimes have gaps,
3 or they are subject to ambiguity or hyper technical reading.
4 Good lawyers defending their clients and representing their
5 clients have to be cautious not to overcommit. I understand
6 that need.

7 That is what I assumed was worked out in the meet and
8 conferral process, it says that, but what we really want is
9 this. We don't need to rewrite it. We agree. The special
10 master is sitting here, we all agree. I assumed that was part
11 of that process, and maybe it was and maybe there is still a
12 misunderstanding.

13 I appreciate your comment, and I will tell you, and I
14 have said this before, I spent a lot of my career doing white
15 collar defense and we would get subpoenas from the Government.
16 Anybody who has ever gotten a subpoena or a request for
17 documents from the Government knows it's essentially every
18 document your company has ever generated from the beginning of
19 time to the present relating to all topics that conceivably
20 might have committed a crime. That's the scope of the
21 subpoena.

22 I would always pick up the phone and call the
23 prosecutor and the first question was, okay, what do you really
24 want and what are you looking for? I assume that is how the
25 meet and conferral process is, okay, we got this, we

1 understand. You have marked your territory, but what do you
2 really want and how do we get there? It sounds like that is
3 the process that is at work here and I appreciate that.

4 Mr. Yoo, what are the PV issues that you think are
5 still ripe for ruling this afternoon?

6 *MS. GOLDENBERG:* Your Honor, I apologize, I don't mean
7 to cut Mr. Yoo off. This is Marlene Goldenberg for the
8 Plaintiffs.

9 I wanted to just note at this point that I disagree
10 with some of the ways that Mr. Yoo has characterized what we
11 now have rulings and agreement on. I am happy to address the
12 issue that he was about to bring up and circle back to the
13 rest, but I just didn't want to let this pass --

14 *THE COURT:* That is fine.

15 *MS. GOLDENBERG:* -- without putting that out there.

16 *THE COURT:* That is fine. I know what my rulings
17 were. You all can disagree about what they were, but I know
18 what I ruled. If there is ambiguity about that I am sure we
19 will find a way to sort that out. No one is waiving anything
20 by sitting patiently and letting the other person talk.

21 Let Mr. Yoo finish up and then, Ms. Goldenberg, I will
22 give you as much time as you need.

23 *MR. YOO:* Thank you, your Honor. Thomas Yoo again for
24 the generic Defendants.

25 I believe the only remaining issue on

1 pharmacovigilance is that the deposition notice defines
2 "regulatory agency" as any regulatory agency globally. It is
3 not what we communicated to the FDA, or what was in our FDA
4 regulatory documents, it is FDA and any other agency anywhere
5 in the world, and we think that is overly broad.

6 And we think that if we literally had to comply with
7 that we would have to go, depending on the Defendant and in how
8 many countries Ranitidine is sold by that Defendant, we have to
9 talk to the regulatory people across the world. I don't think
10 that that is what the Plaintiffs really want. I certainly
11 don't think it is what they need.

12 So, we would request that the regulatory and
13 pharmacovigilance issues be limited to our reports to the FDA,
14 our communications to the FDA.

15 If I am understanding the Plaintiffs' papers
16 correctly, they do have this concern that when they look at our
17 FDA communication documents, at least for some of the
18 Defendants, sometimes they see a reference to things that
19 occurred outside of the U.S.A.

20 Well, to the extent a Defendant reported X U.S. data
21 to the FDA and it is therefore part of the FDA communications,
22 then I think it is fair game. What we don't want to have to do
23 is go talk to our regulatory head in Japan, or the Middle East,
24 or Brazil and find out what is in those documents, because
25 obviously it has nothing to do with our dealings with the FDA.

1 *THE COURT:* Okay. Let me hear from Ms. Goldenberg.

2 *MS. GOLDENBERG:* Sure, your Honor.

3 *THE COURT:* I'm sorry, Ms. Goldenberg, I apologize.

4 Mr. Yoo, your objection there is undue burden and
5 relevance and disproportionality. Am I correct?

6 *MR. YOO:* That is correct, your Honor.

7 *THE COURT:* I apologize, Ms. Goldenberg, for cutting
8 you off. Please.

9 *MS. GOLDENBERG:* No problem, your Honor. This is
10 Marlene Goldenberg for the Plaintiffs.

11 Let me start out by tweaking one thing that Mr. Yoo
12 said. I wanted to point out that our definition of regulatory
13 authority is not what he said it was. What we have asked for
14 is in the chart, but just to paraphrase, we are looking for
15 information that was submitted to the United States FDA and
16 then limited and targeted other agencies.

17 So, we have asked for information from the European
18 Medicines Agency, Health Canada, and then any facility that
19 makes product, or distributes product, or sells product that
20 goes to the U.S.

21 Understanding what we just talked about in the context
22 of storage and shipping, we know, for example, that many of
23 these facilities are located overseas, as you said, in Israel,
24 in India, and other places, and this is a Defendant specific
25 inquiry and we have left it that way in the definition.

1 The reason that we need information from around the
2 world is because pharmacovigilance is different from
3 manufacturing and it is different from storage and handling.
4 The difference is pharmacovigilance involves the study of
5 understanding from a post-market standpoint how the product
6 fares in the real world.

7 Ranitidine, the molecule, is largely the same wherever
8 they send it, whether they send it to Israel or Japan, and
9 people, who are largely the same, live in all of these
10 countries. So, if a person in Israel has an adverse event or
11 they develop cancer because of Ranitidine, it is no less
12 relevant to this case because they live in Israel than if they
13 lived in the United States, and the Defendants agree with that.

14 We cited Teva USA's website in our papers where they
15 talk about their global pharmacovigilance database, and in
16 fact, the Defendants are required to report these
17 global adverse events to the FDA in their filings, and we
18 attached one of those as an example so that you could see that.

19 So, while manufacturing does make sense to confine to
20 the U.S., pharmacovigilance is something that our experts need
21 to be able to look at to make determinations about general and
22 specific causation in this case, and we assume the Defendants'
23 experts are going to be analyzing that very same data.

24 So, prohibiting us from questioning witnesses about
25 this information handicaps Plaintiffs' ability to prove their

1 case, and unless Defendants are going to say they are not
2 looking at any information from other countries, I think that
3 Rule 26 is clear that we are entitled to any information about
4 the defenses they would raise, too.

5 *THE COURT:* Let me clarify again and make sure I
6 understand you, Ms. Goldenberg.

7 Your ask is the U.S., Canada, the EMA, and then any
8 country's regulatory authority where Ranitidine is manufactured
9 which is ultimately sold in the United States. Am I
10 understanding that is the scope?

11 *MS. GOLDENBERG:* Correct, because those countries have
12 authority to inspect those agencies, and so we assume there are
13 documents there that would be relevant.

14 *THE COURT:* Let's assume generic manufacturer -- Mr.
15 Yoo, who is your client? I will pick on your client for a
16 second.

17 *MR. YOO:* Thomas Yoo. My client is Glenmark.

18 *THE COURT:* Let's say Glenmark has a manufacturing
19 facility in Romania and they sell into the E.U. and somebody in
20 Liechtenstein gets cancer from their Romanian produced
21 Ranitidine. Who do they report that to? Do they report that
22 to the regulatory authority in Romania or the regulatory
23 authority in Liechtenstein? Who gets that report? Is it where
24 the adverse event occurred or is it where the drug was
25 manufactured which led to the adverse event, if you know?

1 MS. GOLDENBERG: Is that question for me, your Honor?

2 THE COURT: Yes, for you, Ms. Goldenberg.

3 MS. GOLDENBERG: So, adverse events is an area where I
4 think that information does make its way to the U.S. FDA
5 because the manufacturers have to report that information.

6 What isn't going to make it to the FDA necessarily are
7 the documents that we cited to in our submission. For example,
8 when this whole thing broke and everyone found out that there
9 was NDMA in these pills various regulatory agencies sent out
10 inquiries to the manufacturers asking them to answer some
11 targeted questions, which is what you saw in the document that
12 we submitted.

13 There is an issue there about what happened from a
14 timing sequence. For example, if the European Medicines Agency
15 got to this before the FDA, and the Defendants in those
16 documents concede we have Ranitidine tablets that are
17 contaminated with NDMA, but then we find out that they waited
18 six months to recall that product in the United States, that is
19 an issue that goes to notice.

20 I will tell you I was just involved in a different
21 case where the manufacturer of a pharmaceutical drug warned the
22 EMA and Health Canada five years before they decided to warn
23 the United States. So this is a real thing that actually
24 happens.

25 The other information that doesn't necessarily get

1 there is, again, inspections of these facilities that go to
2 manufacturing issues, and we have seen 483 -- those are what
3 the FDA calls the letters when they inspect them, but other
4 agencies have comparable letters -- saying things to the effect
5 of, this company isn't doing adequate stability testing, which
6 goes directly to the expiration date claims. That is why these
7 facility inspections are also important.

8 One could argue about whether or not they belong in
9 manufacturing topics or PV. I think we have topics that cover
10 both, but we are willing to confine this to the PV notice so
11 that we get this information that is relevant to more than what
12 the Defendants say in their motion.

13 It's not just failure to warn the FDA, this all goes
14 to how the product acts in the real world and whether or not
15 their expiration dates are set properly, whether or not their
16 products are degrading on the market and on shelves and in
17 shipping, and whether or not their storage conditions are
18 adequate.

19 *THE COURT:* Thank you. Let me go back to Mr. Yoo and
20 have him respond.

21 Mr. Yoo, with that clarification from Ms. Goldenberg,
22 that they are not asking every of the 23 generics to report
23 everything they have ever told to every regulator agency in the
24 world about PV, do you have a sense, if it is limited to
25 countries overseas where you have manufacturing facilities,

1 plus the E.U. and Canada, does that affect the burden issue?

2 MR. YOO: It does. Thomas Yoo for the generic
3 Defendants.

4 It does and I can't give you a reliable answer for
5 every country that may be involved for all of the generics
6 without all of us literally speaking to the pharmacovigilance
7 people in those countries. Suffice it to say the regulatory
8 framework is different from country to country, and therein
9 lies a large part of this problem.

10 Let me address, if I can, your Honor, the things that
11 Ms. Goldenberg raised.

12 First, the Plaintiffs' definition in their notice --
13 this is page four of their deposition notice, Exhibit A to our
14 pharmacovigilance motion: Regulatory agency means the United
15 States Food and Drug Administration, or any equivalent
16 regulatory authority globally or in other countries, that is
17 charged with the regulation of RCPs, that is Ranitidine
18 containing products, including, but not limited to the European
19 Medicines Agency, Health Canada and the World Health
20 Organization.

21 So, it is not limited to specific countries, it
22 literally includes anywhere in the world. But even if it were
23 limited to the E.U. and Health Canada, that would still require
24 the Defendants to go work up two separate pharmacovigilance
25 areas, have those witnesses learn those regulatory files,

1 understand what the legal framework is in those regions, and
2 then testify based on those contacts.

3 So, the burden problem is still there, the
4 proportionality problem is still there. And to the extent that
5 there are X U.S. issues that affect the U.S. market such as
6 inspections of manufacturing facilities abroad, the FDA --
7 Ms. Goldenberg will agree with this, the FDA routinely sends
8 people around the world to inspect manufacturing facilities, do
9 reports and all the other things that FDA does for anything
10 that affects the U.S. market.

11 So, those things are going to be contained in the U.S.
12 regulatory files. We don't have to go look at everything in
13 our EMA file or Japanese file to prepare someone to testify
14 about any and all of those communications and regulations. We
15 believe that is not relevant and it's not proportional and
16 shouldn't be permitted here.

17 You know, if Plaintiffs want to come back and
18 demonstrate good cause after they get a U.S. pharmacovigilance
19 deposition and say we have these specific questions and the
20 witness couldn't answer them, and we think we need a second
21 deposition to get to those questions, by all means, but we
22 don't feel we should be burdened with obligations across 20 to
23 30 generics to go talk to our pharmacovigilance people around
24 the world.

25 *THE COURT:* I understand. Ms. Goldenberg, let me go

1 back to you.

2 What are you shooting at here? Are you just trying to
3 establish this is what they said, to try to lay a predicate
4 that -- to your example that you used, if you told the
5 Europeans this causes cancer and you waited to tell the FDA for
6 a year, we have a negligent failure and a failure to tell the
7 FDA -- I forget what count that was -- failure to warn through
8 the FDA, et cetera, et cetera.

9 Is really the relevance of these files simply what was
10 said and you just want a record of what was said and what
11 wasn't said, or is it your intention at the deposition to drill
12 down, well, why didn't you do this, and why didn't you do that,
13 and what procedures did you follow to make sure that you were
14 reporting to the Israeli authority? How deep are you intending
15 to dive on this?

16 *MS. GOLDENBERG:* I am glad you asked that, your Honor,
17 because there is the theoretical fight about this and there is
18 the practical fight about this. The theoretical fight is the
19 one that we have already had, so I am not going to rehash it
20 except to say that Mr. Yoo has our definition wrong because he
21 doesn't have the right notice, and we pointed that out in our
22 chart.

23 Beyond that, every one of these companies has a global
24 head of pharmacovigilance, they all run through the same
25 department. The reason for that is because they have global

1 pharmacovigilance obligations because they have to determine
2 for causation purposes in this case especially, does Ranitidine
3 cause cancer, and the way that you make that assessment is
4 based on the totality of the information available through
5 medical literature and through adverse events.

6 I don't want to get into in a deposition why didn't
7 you tell the Israeli authorities this, I don't have that kind
8 of time. What I do want to get into is what does the totality
9 of the evidence look like, is there a safety signal here, and
10 what did you do to track your adverse events.

11 Because while we have been sitting on this hearing I
12 logged into the U.S. FDA adverse event reporting database and
13 found that in some years there are less than 300 adverse events
14 total being reported for generic Ranitidine, so we are not
15 talking about that many.

16 You know, what information did they collect, how did
17 they collect it, and what did they do with it in terms
18 of adjusting their expiration dates and storage and handling
19 conditions, because this is their real world test for how their
20 product functions.

21 *THE COURT:* Right. I hear you on that and I
22 appreciate that. Just to make sure you and I are talking about
23 the same thing here -- let me put it this way:

24 I think, to the extent what you are asking for is
25 simply what did you say, that's a statement of a party

1 opponent, binding on them, it shows that they were on notice,
2 that they knew certain things and you could lay that against
3 what they have said to the public, or they have said to the
4 FDA, or they have said to other people, and try to make an
5 argument, try to draw an inference that they had knowledge that
6 they were trying to conceal. I am not saying they did, I am
7 just saying, if I understand it, that is sort of the
8 evidentiary trail you want to go down.

9 *MS. GOLDENBERG:* That is part --

10 *THE COURT:* It would seem to me that that would be
11 relevant. Let's start with that. To drill down much deeper
12 than that and get into why didn't you do and why did you do
13 starts, to me, to get farther and farther away from what is
14 really relevant and proportional to the needs in this case.

15 Now, what I think I am inferentially hearing from you,
16 Ms. Goldenberg, is that your impression is -- and I am going to
17 simplify this -- that somebody at Glenmark sitting in the
18 United States can push a button and go into the
19 pharmacovigilance database and get all that. They can find
20 relatively quickly what they told the EMA and what they told
21 the Israelis and what they told the Romanians, and everything
22 else, and that wouldn't be burdensome.

23 But you, I think, would agree that if they have to
24 prep a witness to talk about what are their policies and
25 procedures and practices in every single country for how that

1 reporting gets done and whether that reporting gets done and
2 that kind of thing, the burden starts to increase.

3 So, that's what I am hearing from the two of you, and
4 I think that is what I am being asked to balance, but I want to
5 make sure you have a chance to fairly comment on that.

6 *MS. GOLDENBERG:* Yes. I agree with everything you
7 said so far. The only caveat is, we also want to know, in
8 analyzing the adverse events the Defendants have gotten, how
9 did they use that data, or did they use that data to adjust
10 their expiration dates or to look at their storage and handling
11 obligations, and whether they did anything with that.

12 So, I guess that would be the only thing I'd tack on,
13 but otherwise I agree.

14 *THE COURT:* Temporally, that seems to me -- the point
15 I am focused on is what did they say. Okay. There is a trail
16 of evidence that flows temporally after that, meaning you said
17 that, you knew that, and what did you do with that information.

18 *MS. GOLDENBERG:* Correct.

19 *THE COURT:* And there is a trail of evidence that goes
20 temporally before that, which is what led up to and caused you
21 to do, and how did you, and why did you report that
22 information.

23 *MS. GOLDENBERG:* Right.

24 *THE COURT:* I hear you on the temporally after, but
25 what I hear Mr. Yoo arguing primarily is temporally before.

1 Again, maybe I am missing the argument here so let me turn to
2 Mr. Yoo to educate me if he needs to.

3 *MR. YOO:* I am tracking what you are saying, your
4 Honor, and if I am understanding you correctly, I agree with
5 you. If they want to know what did we tell other regulatory
6 agencies regarding a root cause analysis, for example, they can
7 ask that in an interrogatory and then they can use that
8 interrogatory answer and ask our U.S. pharmacovigilance witness
9 whatever question they want about compare and contrast, why did
10 you tell them this, but you told the FDA that.

11 You are absolutely right, the main burden concern we
12 have is to produce a 30(b)(6) witness on our dealings with
13 regulatory agencies globally would require us to do the whole
14 thing, the legal structure, why we report, when we report, what
15 we report in Israel, Japan, Romania, and to what end other than
16 driving up the costs on our side.

17 At a very minimum, we would be talking about counting
18 each of those as a separate 30(b)(6) deposition because that is
19 not one person.

20 I would also note for the record that it is not
21 correct to say there is a global head of pharmacovigilance at
22 every one of the generic companies who has a laptop and all he
23 or she has to do is press a couple of buttons and the data pops
24 up. That's not how it works.

25 *THE COURT:* No, I understand, I was over simplifying.

1 I understand that. I think I understand the lay of the land
2 here.

3 I will say this, it is an interesting characteristic
4 of the 30(b)(6) witness process that -- and actually you could
5 have one 30(b)(6) pharmacovigilance witness to testify to all
6 of these things, you just have to educate that person. That is
7 the beauty of 30(b)(6), the person doesn't have to have
8 personal knowledge.

9 So, it could be one person, it could be three people,
10 it could be five people, that is entirely up to you, and we'll
11 cross the bridge later as to whether that counts as one
12 deposition, two depositions, or five depositions, but I don't
13 want to dip my toe into that quite yet.

14 Ms. Goldenberg, anything further from you -- I will
15 tell you, my inclination is that what they told these foreign
16 agencies, as limited by your new definition -- not new, but the
17 one that you claim is the correct definition, what they told
18 them is fair game and what they did with that information going
19 forward is fair game. I am not inclined to require them to
20 prep a witness to explain everything that sat behind that in a
21 foreign country.

22 Let me hear you on that before I formalize that as a
23 ruling.

24 *MS. GOLDENBERG:* I think we are fine with that, your
25 Honor. Frankly, the only thing I was going to say is, our

1 topics actually do that for them already. That goes back to my
2 there is the theoretical fight and there is the actual
3 practical fight.

4 So, the topics that we have given that implicate
5 regulatory agencies ask for very targeted and specific things
6 like risk management plans, health hazard analyses, and I think
7 those all go to what you were just saying about what they told
8 those regulatory authorities about things that matter to this
9 case.

10 *THE COURT:* All right. Mr. Yoo, anything further you
11 would like to be heard on?

12 *MR. YOO:* Your Honor, unfortunately, if we have to
13 provide information related to EMA and Health Canada, for
14 example, what that information is that we would be required to
15 provide I think is important.

16 Number 14 on their pharmacovigilance deposition notice
17 is incredibly broad. I think we would have to be very specific
18 about what we have to prepare a witness on or what
19 interrogatory response we would have to provide.

20 Currently, number 14 says any evaluations, analyses,
21 discussions, recommendations, statistical analyses or reports
22 pertaining to Ranitidine containing products and/or H2 blockers
23 and NDMA, N-nitrosamines, nitrite, dimethylamine, genotoxins,
24 Class 1 residual solvents, precancer, cancer markers, cancer,
25 carcinogenicity, nitrosation, tumor development, tumor inducer

1 and/or tumor promoter.

2 *MS. GOLDENBERG:* Once again, I am sorry to cut in, but
3 Mr. Yoo has an old notice.

4 *THE COURT:* Is that not the operative notice? Okay.
5 I will tell Mrs. Stipes that is in a document that she will
6 have, so she will get the proper spellings from the document.

7 Ms. Goldenberg, what, in your view, is the correct
8 document I should be looking at? Was it the one attached to
9 your submission, not to the Defendants' submission?

10 *MS. GOLDENBERG:* Correct.

11 *THE COURT:* Hold on, let me pull that up.

12 *MS. GOLDENBERG:* I could read it into the record, but
13 I think Ms. Stipes might be angry at me if I do.

14 *THE COURT:* Hold on. I don't think I -- I have it
15 somewhere else.

16 *MS. GOLDENBERG:* I am happy to read it if that's
17 easier.

18 *THE COURT:* Here is my point. I don't think I need
19 you to read it. I think that starts to get more granular than
20 I am comfortable ruling on in advance on a 30(b)(6). I think
21 further meet and conferral -- it sounds to me like again the
22 notice is written in a way to be overly inclusive, as they
23 always are. Mr. Yoo is being a good lawyer and reading it very
24 strictly and going to try and make his client comply with the
25 obligations that would otherwise be imposed if the Court

1 construes it strictly.

2 I think we all understand, as Ms. Goldenberg has said,
3 in the real world this case is about Ranitidine, it's about
4 whether the companies were on notice that Ranitidine decomposes
5 into a carcinogen, and that carcinogen causes cancer. That is
6 the bulls-eye that I assume number 14 is shooting at, what did
7 you tell these agencies about that kind of stuff?

8 Am I right, Ms. Goldenberg?

9 *MS. GOLDENBERG:* Yes.

10 *THE COURT:* I would agree, and I assume Mr. Yoo would
11 agree, that if it is limited in that general fashion they would
12 not object and they would prepare a witness for that. If you
13 all need to wordsmith the language to memorialize that sort of
14 scope, but I think that is a reasonable scope.

15 *MS. GOLDENBERG:* Noted.

16 *THE COURT:* Does that address your concern, Mr. Yoo?

17 *MR. YOO:* Yes, your Honor. We will work with that and
18 continue to discuss with Plaintiffs.

19 *THE COURT:* Very good. It is one of those situations
20 where everyone understands what we are trying to define.
21 Sometimes putting that into words is a little difficult, which
22 is why lawyers get paid a lot of money to try to write things
23 down. I am confident that, having worked with both of you for
24 over a year now, you will be able to get there. If not, you
25 can come back to me or the special master and we will nail it

1 down.

2 Mr. Yoo, to the extent your concern is, if we reported
3 that tobacco causes cancer and tobacco is a carcinogen, we now
4 have to turn over all of our tobacco related communications, no
5 one thinks that is what this is going to cover. I don't think
6 that's what it is intended for and it is certainly not my
7 ruling that you would have to turn over anything like that.

8 If that is your concern, I will allay that concern.

9 MR. YOO: Thank you, your Honor.

10 THE COURT: Very well. Mr. Yoo, is there anything
11 else in the motion that you wanted to address this afternoon?
12 Neither side waiving any objections to rulings I may have
13 already made.

14 MR. YOO: No, your Honor, nothing that has not already
15 been covered. Thank you very much for your time.

16 THE COURT: Thank you all very much.

17 It is barely 4:30, good, we are in under budget here.

18 I shudder to ask this question, but I feel compelled
19 to always ask this question. While we are all together this
20 afternoon, is there any other issues that we need -- let me
21 look at my notes.

22 Any of the submissions that I have referenced that I
23 relied on, the parties' submissions, should all been filed in
24 the docket. The attachments, if they were marked confidential
25 should be filed under seal. If they were not marked

1 confidential they do not have to be filed under seal.

2 We have scheduled another hearing for Thursday at one
3 o'clock relating to the -- for other issues related to the
4 generic manufacturing. We scheduled a hearing for Monday --
5 what time on Monday did I schedule this for, Ms. Finken?

6 *MS. GOLDENBERG:* I think you said it was four o'clock,
7 Your Honor, but I will let Tracy correct me if I'm wrong.

8 *THE COURT:* I don't think so. I don't usually
9 schedule things that late in the day. So, 2:00 to 4:00 for
10 that. Okay.

11 I have ruled on everything everyone wanted me to rule
12 on today. Everybody has preserved all of their objections.

13 Let me do this if I can, I hate to burn everybody's
14 billable time. Let's take a five minute break. I want to
15 review my notes, make sure there is nothing else I wanted to
16 talk to you about today. If not, we will recess and I will let
17 everybody go.

18 It is 4:37. How about we come back at 4:45, and you
19 all think about if there's anything else that you wanted to
20 raise while we're together today. We will be in recess until
21 4:45.

22 *MS. FINKEN:* Thank you, your Honor.

23 *(Thereupon, a short recess was taken.)*

24 *THE COURT:* Let's go back on the record. I am waiting
25 for Ms. Finken. Ms. Goldenberg, you will have to stand in for

1 a second.

2 Let me ask the generic Defendants, any problem if I
3 move the hearing on Thursday from one o'clock to 12:30?

4 *MR. HENRY:* Your honor, Terry Henry for Apotex. There
5 is no problem on this end.

6 *THE COURT:* Okay. Ms. Goldenberg?

7 *MS. GOLDENBERG:* No problem with me, but I would like
8 Ms. Finken to make sure that she can confirm the same.

9 *MS. THOMPSON:* Your Honor, Sara Thompson for Teva. I
10 am not available on Thursday due to a conflicting hearing, but
11 I don't think I am, hopefully, necessary.

12 *THE COURT:* Okay. You are going to trust Mr. Henry
13 and Mr. Yoo to carry the water for you?

14 *MS. THOMPSON:* Correct, your Honor.

15 *THE COURT:* Thank you, Ms. Thompson. Subject to
16 Ms. Finken weighing in, we will move the hearing to 12:30 for
17 Mrs. Stipes to be with Judge Rosenberg at 2:30.

18 Other than that, Ms. Goldenberg, anything else that
19 you wanted to raise on behalf of either yourself or your
20 clients today?

21 *MS. GOLDENBERG:* No, your Honor, and Tracy and I
22 talked off line, and we agreed there is nothing else from the
23 Plaintiffs, although she is now here to weigh in on the
24 schedule.

25 *THE COURT:* Okay. Ms. Finken, I was going to move the

1 hearing on Thursday from one o'clock to 12:30.

2 *MS. FINKEN:* That is fine.

3 *THE COURT:* Great, we will do that. No other issues
4 from the Plaintiffs. Mr. Yoo, Mr. Henry, or Ms. Thompson, any
5 other issues on behalf of the generic manufacturers this
6 afternoon?

7 *MR. YOO:* Nothing from us, your Honor.

8 *MR. HENRY:* No, your Honor.

9 *MS. THOMPSON:* No, your Honor.

10 *THE COURT:* Thank you all very much, extremely well
11 argued, extremely well briefed and very helpful. I will look
12 forward to seeing some of you on Thursday, some of you on
13 Monday, and all of you at our next discovery status a week from
14 tomorrow.

15 Thank you, everybody. Have a good afternoon. We will
16 be in recess.

17 (Thereupon, the hearing concluded.)

18 * * *

19 I certify that the foregoing is a correct transcript
20 from the record of proceedings in the above matter.

21
22 Date: March 5, 2021

23 /s/ Pauline A. Stipes, Official Federal Reporter

24 Signature of Court Reporter

25
Pauline A. Stipes, Official Federal Reporter

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